Attachment 18

RAI SERVICES COMPANY

Mitchell A. Neuhauser
Vice President
Assistant General Counsel - Regulatory

401 North Main Street
Winston-Salem, NC 27101
336.741.7500
neuhaum@rjrt.com

October 11, 2019

VIA ELECTRONIC SUBMISSION
AND HAND DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-3065 ("Tobacco Products; Required Warnings for Cigarette Packages and Advertisements")

Dear Sir or Madam,

On August 16, 2019, the U.S. Food and Drug Administration ("FDA" or "the Agency") issued a proposed rule regarding graphic warnings for cigarette packaging and advertising. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754 (Aug. 16, 2019). In response, RAI Services Company ("RAIS") respectfully submits these comments on its own behalf and on behalf of its affiliated tobacco companies.[1]

RAIS supports promoting public awareness of the harms of smoking cigarettes, including through appropriate warnings on tobacco products. RAIS is committed to working cooperatively with FDA to address this important public-health issue, and submits these comments in the spirit of advancing that shared goal.

Executive Summary

For decades, the government has used a multi-pronged approach to reducing smoking. First, the government has required that cigarette packages and advertising contain factual warnings about the health risks of smoking and other information. *See, e.g.*, Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965); Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2,200 (1984); Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1,776 (2009). Second, the government has systematically limited the

[1] RAIS coordinates regulatory compliance for Reynolds American Inc.'s ("RAI") subsidiary companies, including R.J. Reynolds Tobacco Company; American Snuff Company, LLC; Santa Fe Natural Tobacco Company, Inc.; and R.J. Reynolds Vapor Company. References to RAIS or "the Company" in this letter may refer to RAIS itself and/or its affiliated RAI subsidiaries, as applicable.

avenues through which cigarette manufacturers can speak to adult smokers. For example, federal law prohibits cigarette companies from advertising through television or radio, and severely restricts them from selling or giving away branded merchandise, sponsoring events, and giving out free samples. 15 U.S.C. § 1335; 21 U.S.C. § 387a-1. Third, the government has run multiple public-health campaigns that informed the public about the health risks of smoking and urged smokers to quit. For example, the Surgeon General has published more than thirty reports on smoking and health, and between 2009 and 2014, FDA alone spent more than $500 million on anti-smoking campaigns. *See infra* pp. 13–14, 32.

This multi-pronged approach—requiring factual warning labels on every cigarette package and advertisement, advertising restrictions, and government advocacy—has been extremely successful at reinforcing and sustaining effectively universal public awareness of the dangers of smoking. In 1999, the Centers for Disease Control and Prevention ("CDC") recognized that the public widely understood the risks of smoking, and declared that understanding to be one of the ten greatest public health achievements of the twentieth century. CDC, *Ten Great Public Health Achievements—United States, 1900–1999* (Apr. 2, 1999), https://tinyurl.com/y8wfy53b.[2] Today, the public still universally understands those risks. For example, data from FDA's Population Assessment of Tobacco and Health ("PATH") survey shows that 99.5% of individuals believe that cigarette smoking is harmful to health, including 91% who believe that it is "very or extremely harmful," 7% who believe it is "somewhat harmful," and 1.5% who believe it is "slightly harmful." Klick Report ¶ 5.20; *see also infra* Section I.B.6(a).

Moreover, smoking prevalence and cigarette consumption are both down. Between 1965 and 2017, the percentage of adults who smoked cigarettes fell from 42.4% to 14%. Between 1981 and 2017, the number of cigarettes purchased annually in the United States dropped from 640 billion to 249 billion—a decline of more than 60% despite an increase in the U.S. population of more than 100 million. And between 1997 and 2018, the percentage of high school students who smoked fell from 36.4% to 8.1%. *See* 84 Fed. Reg. at 42,758 ("[C]igarette smoking prevalence has generally declined over the past several decades[.]"). Indeed, youth and adult smoking rates are at historic lows. *See infra* p. 23.

Despite this success, however, a small percentage of Americans choose to continue smoking. Frustrated by that reality, FDA has decided to change tacks: instead of informing the public about smoking risks as it has done to date, the Agency plans to force cigarette *manufacturers* to convert their packaging into a government-controlled, anti-smoking communication tool. And instead of using factual warnings, the Agency plans to force manufacturers to use gruesome and exaggerated images—essentially compelling manufacturers to disparage their own products, and frighten and shame their own customers.

The first time FDA issued a graphic-warnings rule, the Agency was clear about its motives. FDA admitted that the point of graphic warnings was to "rebrand[] our cigarette packs"; convey that "smoking is gross"; "dispel[] the notion that somehow [smoking] is cool"; and "encourage smokers to quit." Press Briefing by Press Secretary Jay Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011),

[2] All web addresses in these comments have been shortened using TinyURL, which results in a web address that contains "tinyurl.com."

https://tinyurl.com/yyxc8x88. Indeed, FDA admitted that graphic warnings were designed to make "'every single pack of cigarettes in the country a mini billboard' for the government's anti-smoking message." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1212 (D.C. Cir. 2012) (quoting FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010)). This time around FDA has decided to be less transparent, saying that it merely wants to "promote greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. But this "contrived" rationale cannot disguise the Agency's real goal. *See Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575–76 (2019).

The proposed rule would mandate that manufacturers use the top 50% of the front and back of cigarette packages, and at least the top 20% of cigarette advertisements, to present the government's anti-smoking messages. And the proposed rule does *not* restrict itself to requiring the disclosure of factual information that would enable smokers to make better-informed decisions. To the contrary, the warnings use gruesome, inflammatory images that are plainly designed to evoke negative emotions, such as fear, disgust, and distress. In short, the warnings are supposed to trumpet the government's preferred ideological message: don't smoke. *See infra* Section I.B.1.

The First Amendment flatly forbids FDA's attempt to commandeer manufacturers' speech in order to remove a "popular but disfavored product from the marketplace." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 577–78 (2011). Specifically, the Tobacco Control Act's graphic-warnings requirement and the proposed rule violate the First Amendment in the following ways:

First, FDA has not identified a legally sufficient governmental interest to justify this extreme rule. FDA says that it wants to "promote greater public understanding of the negative health consequences of cigarette smoking." 84 Fed. Reg. at 42,755. But this information is not necessary to prevent consumer deception, and it will not have any real-world effect on how consumers behave. In other words, FDA wants to give people information for information's sake. As the D.C. Circuit has already held, however, "FDA's interest in 'effectively communicating' the health risks of smoking is merely a description of the means by which it plans to accomplish its goal of reducing smoking rates, and not an independent interest capable of sustaining [a graphic-warnings rule]." *R.J. Reynolds*, 696 F.3d at 1221; *see also infra* Section I.B.4–5.

Second, even if FDA's asserted interest were valid, the proposed rule would not advance it. FDA says that it wants to increase public understanding by correcting various "misperceptions" that the public supposedly has about smoking. But that is a purely hypothetical problem. Multiple data sources demonstrate that the public already knows that smoking is harmful and can cause serious diseases. Indeed, this fact is illustrated by FDA's decision *against* using several of the warnings prescribed by Congress in the Tobacco Control Act, such as "Smoking can kill you," because they do not tell the public anything that it does not already know. *See infra* pp. 14–15.

FDA tries to sidestep this problem by adopting warnings that supposedly focus on "less-known health consequences of smoking." 84 Fed. Reg at 42,755. Yet the proposed rule fails to demonstrate that the public does not understand these risks. Once again, PATH data and other surveys show widespread public awareness of many of the risks that FDA describes as "less-known." And FDA does shockingly little to contradict those surveys—indeed, virtually every study that FDA cites is outdated, focuses on foreign countries, or focuses on a smoking risk that FDA decided not to address in the proposed rule. Most importantly, in the proposed rule, FDA

effectively concedes that the public knows many of the risks identified in the proposed warnings, such as the risks of secondhand smoke, lung disease, strokes, and heart disease. *See infra* pp. 15–18.

Moreover, even if the public lacked sufficient understanding of some less-known risks, FDA cannot show that graphic warnings would remedy that problem. As explained above, graphic warnings evoke negative emotions such as fear, shame, and disgust. But the "empirical evidence on the use of emotional appeals in warnings is mixed at best." Klick Report ¶ 5.81. FDA's second consumer research study confirms the point. In that study, FDA tested participants' health beliefs ("Session 1"), showed them the proposed warnings, and then tested their health beliefs one day later ("Session 2") and fourteen days later ("Session 3"). At the end of that process, five of the warnings had actually *reduced* the participants' knowledge about the relevant health risks, and seven of the remaining eight warnings saw sharp decreases in knowledge gains between Session 2 and Session 3. *See infra* pp. 18–20.

Even worse, FDA cannot show that the warnings would meaningfully change how people think about the overall risk of smoking or whether they smoke. Dr. Jonathan Klick, a leading expert on the causal effects of health regulations on behavior, analyzed PATH data to determine whether smokers find the risks identified in the proposed warnings to be material. The answer was a resounding no. Klick Report ¶ 5.29–40. Indeed, Dr. Klick's analysis shows that awareness of the particular risks that relate to the FDA's proposed warnings has no effect on smoking behavior and generally has no effect on overall risk assessment. *Id.* ¶ 5.37. This result is devastating to the proposed rule's "information for information's sake" rationale; FDA therefore chose *not* to rely on this PATH data, even though the PATH survey was "started explicitly to inform the FDA's regulatory decisions and actions with respect to smoking." *Id.* ¶ 5.18; *see also infra* pp. 20–22.

Finally, FDA cannot show that the proposed warnings would reduce smoking. In the first graphic-warnings rule, FDA argued that the warnings would "decrease smoking initiation and increase smoking cessation." *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,628, 36,719 (June 22, 2011). But FDA failed to produce even a "shred of evidence" that the warnings would have that effect. *R.J. Reynolds*, 696 F.3d at 1219. Indeed, FDA's own study determined that the warnings would reduce smoking rates by a mere 0.088%, a number that FDA conceded was "not statistically distinguishable from zero." 76 Fed. Reg. at 36,775–76. Nothing has changed in the past eight years, and FDA has not even *tried* to demonstrate otherwise.

Third, the Tobacco Control Act's graphic-warnings requirement and the proposed rule are insufficiently tailored. The warnings would dominate cigarette packaging: occupying 50% of the front and back panels with identical FDA messages, and using frightening images that are designed to pull people's attention away from the rest of the pack. The combined effect of these requirements would harm cigarette manufacturers' ability to communicate with their consumers. The proposed rule would seize a huge portion of every cigarette package to convey the government's own anti-smoking message. That message would occupy the most prominent part of the package—and often the only part of the package that consumers could see. Thus, when adult cigarette consumers look at a pack of cigarettes, they will see only one thing: the government's anti-smoking message. Those are huge burdens, and they render cigarette packaging—one of the last remaining mediums for cigarette manufacturers to communicate with their consumers—much less effective. *See infra* pp. 25–31.

Moreover, FDA has many less-restrictive alternatives to achieve its goals. For example, FDA could have achieved its goals of bringing attention to "less-known health consequences of smoking" simply by changing the text of the Surgeon General's warnings. Or FDA could have run a public-education campaign about the risks of smoking—an option that the Agency has repeatedly promoted as "highly successful" and "yielding tremendous results." Norman E. Sharpless, *Press Announcement* (Aug. 20, 2019), https://tinyurl.com/y3kmouoa. Indeed, the same week that FDA issued the proposed rule, FDA touted a study asserting that its *Real Cost* youth anti-smoking campaign has "prevented up to 587,000 youth nationwide from initiating smoking between the campaign's launch in February 2014 and November 2016, half of whom might have gone on to become established smokers." *Id.* FDA has demonstrated its ability to deliver public-health messages, including regarding tobacco health risks, and thus had every reason to try to do so here as well. *See infra* pp. 31–34.

In addition to violating the First Amendment, the proposed rule has other fatal flaws. The proposed rule violates the Tobacco Control Act by changing the language of the textual warnings, as well as the total number of warnings, without authority. *See infra* Section II. The proposed rule also violates the Administrative Procedure Act in multiple ways. *See infra* Section III. For example, FDA relied on an inadequate cost-benefit analysis, which failed to quantify the benefits of the proposed rule. The Agency recognized that "there is a high level of uncertainty around quantitative economic benefits"—a fancy way of saying that the proposed rule might not have any benefits at all. Faced with that possibility, FDA did not even *try* to calculate the benefits. *See infra* Section III.A.

As another example, FDA has not given the public a meaningful, legally sufficient chance to comment on the proposed rule. FDA has been working on the proposed rule for years. During that time, FDA had plenty of opportunities to tell the public what it was doing or share its ongoing research—indeed, RAIS's outside counsel tried to get the Agency to do precisely that in June 2017 by submitting a Freedom of Information Act (FOIA) request. But FDA has obfuscated every step of the way: refusing to respond to the FOIA request, refusing to release the results of its consumer research studies, and even asking the public to comment on its final graphic-warnings study *without telling the public which graphic warnings it was testing*. That obfuscation has continued with the proposed rule: FDA again refused to release any information about its qualitative studies and has not released the underlying data from its quantitative studies, all of which were critical to the development of the proposed warnings. To top it all off, FDA has given the public a mere 60 days to come up with alternative graphic warnings—a process that took the Agency more than six years to complete—which would, of course, be impossible. *See infra* Section III.D.

FDA's approach up to this point demonstrates that the Agency has no interest in working collaboratively with the public on this issue. FDA has failed to keep the public informed. And FDA has given the public insufficient time to come up with alternative graphic warnings, perhaps because the Agency does not plan to consider those alternatives. This is the same dismissive approach that FDA took when developing the first graphic-warnings rule, an approach that led directly to that rule's downfall. *See R.J. Reynolds*, 696 F.3d at 1210, 1219–20.

The Tobacco Control Act's graphic-warnings requirement violates the First Amendment, and FDA has exacerbated the problem by issuing a proposed rule that violates the First Amendment, the Tobacco Control Act, and the Administrative Procedure Act. FDA has only one

option: withdraw the proposed rule and refuse to enforce the unconstitutional graphic-warnings requirement.

COMMENTS

I. THE TOBACCO CONTROL ACT'S GRAPHIC-WARNINGS REQUIREMENT AND THE PROPOSED RULE VIOLATE THE FIRST AMENDMENT.

FDA's proposed rule, and the provision of the Tobacco Control Act that requires it, suffer from a fundamental problem: they violate the First Amendment. Neither can survive strict scrutiny because they are not narrowly tailored and because the government lacks a compelling interest. They also cannot survive the *Zauderer* standard for a host of reasons: the warnings are not "purely factual" because they are intended to evoke an emotional response and convey an ideological, anti-smoking message; the warnings are "controversial" because they are misleading and inflammatory; the warnings are "unjustified" because they do not remedy a real-world harm; the warnings are "unduly burdensome" because they commandeer 50% of cigarette packaging and at least 20% of cigarette advertisements for gruesome images; and the government does not have a substantial interest in telling people things they already know or giving people information for information's sake. The Act's graphic-warnings requirement and the proposed rule cannot survive the *Central Hudson* standard for similar reasons.

A. The graphic-warnings requirement and the proposed rule are subject to strict scrutiny, a standard they cannot possibly meet.

1. "Since *all* speech inherently involves choices of what to say and what to leave unsaid, one important manifestation of the principle of free speech is that one who chooses to speak may also decide what not to say." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995) (citations and quotation marks omitted). Thus, the "general rule" is that the government "may not compel affirmance of a belief with which the speaker disagrees." *Id.* This rule "applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid." *Id.* And it applies to "ordinary people" and "business corporations" alike. *Id.* at 574. "For corporations as for individuals, the choice to speak includes within it the choice of what not to say." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 16 (1986) (plurality op.).

In light of these principles, courts generally apply strict scrutiny to government-compelled speech. *See, e.g.*, *Wooley v. Maynard*, 430 U.S. 705, 714–15 (1977); *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226–27 (2015). Under strict scrutiny, the government must prove that the compulsion "furthers a compelling interest and is narrowly tailored to achieve that interest." *Reed*, 135 S. Ct. at 2231.

Here, the Tobacco Control Act's graphic-warnings requirement and the proposed rule would compel manufacturers to express the government's preferred anti-smoking message. *See R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1211 (D.C. Cir. 2012) (holding that FDA's initial graphic-warnings rule "contain[ed] elements of compulsion and forced subsidization" and was therefore subject to First Amendment scrutiny), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 31 (D.C. Cir. 2014) (en banc). The graphic-warnings requirement and the proposed rule are therefore subject to strict scrutiny.

Annual Report to the National Institutes of Health Regarding Grant Funding (Mar. 16, 2016) (attached as Exhibit O). He acknowledged that graphic warnings triggered a sharp emotional response, and described that response as an "indicator[] of greater message engagement and greater effectiveness." *Id.* at 7. The researcher explained that this point was "important because the legal case against implementation of graphic warnings in the [United States] was partly argued on the basis of their emotional appeal, as though it is possible to strip away affect and effectively communicate information." *Id.* He concluded, however, that "[t]hese and other studies we are conducting suggest otherwise." *Id.* In other words, this researcher frankly admitted that it is *impossible* to "strip away" emotion from graphic warnings and still "effectively communicate information."

b. FDA's proposed warnings likewise fail the "purely factual" test. To take just a few examples, the proposed warnings include a picture of diseased feet with several amputated toes, a picture of a woman with a massive cancerous lump on her neck, and two pictures of blackened, diseased lungs. As a litany of news outlets have recognized, these graphic warnings are plainly designed to scare, shame, and disgust people, and to convey an ideological, anti-smoking message, just like their predecessors. For example:

- The Washington Post called the warnings "scary" and "unsettling," and noted that the D.C. Circuit previously struck down "similarly graphic labels." Lindsey Bever, *FDA's Proposed New Cigarette Warnings Are Scary. That's the Point*, Washington Post (Aug. 15, 2019), https://tinyurl.com/y4zuqssj.

- The New York Times called the warnings "disturbing." Sheila Kaplan, *The F.D.A.'s New Cigarette Warnings Are Disturbing. See for Yourself.*, N.Y. Times (Aug. 15, 2019), https://tinyurl.com/y366q2l5.

- Psychiatry Advisor called the warnings "gruesome." Psychiatry Advisor, *FDA Proposed Graphic Warning Labels on Cigarettes* (Aug. 26, 2019), https://tinyurl.com/yyvket6w.

- The Huffington Post called the warnings "ghastly" and "grisly reminders of what could happen to [smokers'] bodies," and described the proposed rule as FDA's "latest plan to deter smokers from lighting up." Amy Russo, *FDA Unveils New Round Of Ghastly Cigarette Warnings In Anti-Smoking Push*, HuffPost (Aug. 16, 2019), https://tinyurl.com/y34tm2sd.

The public has gotten the message. Indeed, when asked what message the proposed warnings send, several respondents said the following:

- "The government is using scare tactics to obtain control over the population."

- "trying to scare people"

- "im grossed out"

2. Graphic warnings are not "uncontroversial" because they are misleading and use inflammatory images.

a. *Zauderer* also requires that compelled disclosures be "uncontroversial." 471 U.S. at 651. A disclosure is "controversial" if it is potentially inaccurate or misleading. *See Entm't Software*, 469 F.3d at 652 (holding that a disclosure was "controversial" because the speaker might reasonably disagree with the message); *R.J. Reynolds*, 696 F.3d at 1216 (holding that FDA's graphic warnings did not fall within *Zauderer* because, among other reasons, "many of the images chosen by FDA could be misinterpreted by consumers").

Here, the proposed warnings are inaccurate or misleading in a number of respects. Several of the images exaggerate the effects of the diseases they purport to represent, exaggerate the likelihood of those diseases being caused by smoking, or offer a misleading portrayal of the treatment of those diseases. In particular:

- The warning pertaining to macular degeneration misrepresents the treatment for that condition. It depicts a far thicker needle than is used in reality, and it depicts the needle being inserted in the center of the eye, rather than in the lower outer area of the eye (where it is typically inserted in reality). *See* Dr. Davidorf Declaration at 2 (attached as Exhibit H). As a result, the warning "may give rise to the false impression that the treatment is painful," when in reality it is not. *Id.* This has the pernicious potential to "frighten[] patients away from beneficial treatment." *Id.*; *see also* Am. Optometric Assoc. Comments, Docket No. FDA-2019-N-3065, at 3 (Oct. 15, 2019) (explaining that this warning will "create fear and distance between patients and necessary medical interventions and/or treatments").
- The warning pertaining to cataracts is "not a reasonable depiction of persons with cataracts in the US, because in the US the cataract would have been treated surgically long before it got to this stage." Dr. Davidorf Declaration at 3. In addition, the image misleadingly "makes the cataract look like a cosmetic problem," when in reality "[t]he vast majority of patients who undergo cataract surgery in the US have cataracts that are undetectable by the unaided human eye." *Id.*
- The warning pertaining to head and neck cancer is likewise "unlikely [to] be accurately understood" by the public. Dr. Jones Declaration ¶ 4 (attached as Exhibit J). The image is misleading to the extent it suggests that "a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point." *Id.* ¶ 5.
- The warning pertaining to lung disease in nonsmokers suffers from "two major flaws." Dr. Farber Declaration ¶ 4 (attached as Exhibit I). First, "the lungs do not look like a non-smoker's lungs." *Id.* In particular, the image depicts an "amount of black pigmentation" that "would likely result from many years of heavy direct smoking" and would be "very unusual … in a non-smoker." *Id.* ¶ 5. Second, its depiction of lesions is both "ambiguous" and "inaccurate." The warning is unclear whether the lesions were meant to depict lung cancer. If so,

the image is misleading because the lesions appear on the surface of the lung (rather than deep within the lung), and because it would be "unusual" for a non-smoker to have three separate lesions of the size depicted. *Id.* ¶¶ 5, 6.

- The warning pertaining to blood flow to the limbs is misleading because it depicts a condition that could affect, at most, one in 1,000 smokers. Dr. Wagmeister Declaration ¶ 4 (attached as Exhibit K).
- The warning pertaining to fetal growth is misleading because it shows a newborn infant weighing four pounds. But according to the U.S. Surgeon General, the low range of normal birth weight is 2,500 grams, and infants born to women who smoke cigarettes weigh approximately 200 grams less than infants born to non-smoking women. CDC, *The Health Consequences of Smoking: A Report of the Surgeon General* 555 (2004), https://tinyurl.com/y4gb8e4c; CDC, *How Tobacco Smoke Causes Disease: the Biology and Behavioral Basis for Smoking Attributable Disease: A Report of the Surgeon General* 538 (2010), https://tinyurl.com/y5wewxku. Thus, conservatively assuming that a normal birth weight of 2,500 grams (the low end of normal birth weight for infants) is decreased by 200 grams due to cigarette smoking, the resulting birthweight is 2,300 grams, or more than five pounds.
- The warning pertaining to heart disease and strokes depicts a man who has had recent open heart surgery, presumably coronary artery bypass grafting (CABG). But recent data reveal that open-heart CABG surgery is not the most common procedure for treating coronary artery disease. Instead, in-patient percutaneous coronary interventions (PCIs), are 2.5 times more common. American Heart Association, *Heart Disease and Stroke Statistics, 2019 Update* e513 (2019), https://tinyurl.com/y8rcqwdb. And this does not account for the significant number of PCIs that are performed on an out-patient basis. *Id.* at e511. Moreover, the use of CABG has been declining over time. *Id.*
- The warning pertaining to harm to children appears to depict a "worst case scenario": "a child hospitalized due to an asthma attack caused by environmental tobacco smoke." Dr. Brooks Declaration ¶ 4 (attached as Exhibit G). To the extent the warning is intended to depict an oxygen mask, it is "exaggerating" because it is "uncommon for a child with an asthma attack to require oxygen." *Id.* ¶ 5. Moreover, only about eight percent of children have asthma, and only five to six percent of children with asthma are hospitalized each year (and of course there are many potential causes of such hospitalizations besides environmental tobacco smoke, such as air pollution and allergens). *Id.* ¶¶ 7–8.

FDA acknowledges that the warnings should not address "rare" diseases, and that the images should depict "disease states and symptoms as they are typically experienced." 84 Fed. Reg. at 42,767, 42,770. As the medical evidence discussed above demonstrates, however, FDA has ignored its own advice.

b. In *R.J. Reynolds*, the D.C. Circuit held that FDA's first graphic warnings failed the *Zauderer* test because they "could be misinterpreted by consumers." 696 F.3d at 1216. In the

proposed rule, FDA again says that it "carefully considered" the court's holding and went through a "science-based, iterative research process" to "thoroughly address[] any such criticisms." 84 Fed. Reg. at 42,777–78. But the proposed rule again belies FDA's assertion.

FDA first tries to rely on a series of focus groups, in which consumers allegedly "provided qualitative feedback on [their] comprehension of each potential statement." 84 Fed. Reg. at 42,778. But FDA has not provided *any* information about those focus groups, so FDA cannot rely on them here. FDA next points to the two consumer research studies that it performed. *Id.* But neither study tested whether the proposed warnings are misleading. Those studies tested whether the warnings conveyed "new information" or whether consumers "learned something" from the warnings, but FDA did *not* ask respondents *what* information the warnings conveyed or *what* the respondents learned. Thus, the studies cannot rebut the evidence above that the proposed warnings are misleading.

c. A compelled disclosure is also "controversial" if it is inflammatory. *See Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018) ("*NIFLA*") (noting that a compelled disclosure involved abortion—which was "anything but an 'uncontroversial' topic"—and that *Zauderer* therefore did not apply); *Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 165–66 (D.D.C. 2018) (explaining that an "inflammatory" disclosure would be "controversial" under *Zauderer*). That means that graphic warnings are *necessarily* inflammatory. As explained above, the Tobacco Control Act requires FDA to adopt images that "depict[] the negative health consequences of smoking." 15 U.S.C. § 1333(d). Such images will *always* evoke negative emotions like fear, shame, and disgust, which means that those images will *always* be inflammatory. Thus, *Zauderer* does not apply to the graphic-warnings requirement or the proposed rule.

3. Graphic warnings do not disclose information about "the terms under which services will be available."

In *Zauderer*, the Supreme Court upheld a compelled disclosure because it involved "purely factual and uncontroversial information *about the terms under which [an attorney's] services will be available*." 471 U.S. at 651 (emphasis added). The Court recently confirmed that this is an essential limit on *Zauderer*. *See NIFLA*, 138 S. Ct. at 2372. In *NIFLA*, the Court explained that *Zauderer* did not apply because the compelled disclosure at issue was "not limited to purely factual and uncontroversial information about the terms under which services will be available." *Id.* (ellipsis and quotation marks omitted). Indeed, the Court explained that the disclosure "in no way relates to the services that [the speakers] provide," and "[a]ccordingly, *Zauderer* has no application here." *Id.*; *see also id.* (citing *Hurley*, 515 U.S. at 573, for the proposition that "*Zauderer* does not apply outside of these circumstances").

Likewise, a Ninth Circuit judge recently recognized that *Zauderer* is limited to disclosures about "the terms on which … advertisers provide their services." *Am. Beverage Ass'n v. City & Cty. of San Francisco*, 916 F.3d 749, 761 (9th Cir. 2019) (Ikuta, J., concurring). Because of that limitation, Judge Ikuta concluded that *Zauderer* did not apply to a compelled disclosure about "sugar-sweetened beverages, which is a product rather than a service." *Id.*

Applying that logic here, *Zauderer* does not apply to the graphic-warnings requirement or the proposed rule. The graphic-warnings requirement does not involve a disclosure "about the terms under which *services* will be available." *Zauderer*, 471 U.S. at 651 (emphasis added). Instead, it applies to cigarettes, which are "a product rather than a service." *Am. Beverage*, 916 F.3d at 761. *Zauderer* is therefore inapplicable.

4. Graphic warnings are not "reasonably related to the government's interest in preventing deception of consumers."

The Tobacco Control Act's graphic-warnings requirement and the proposed rule fail to satisfy *Zauderer* for another reason: they are not reasonably related to preventing consumer deception. In *Zauderer*, the Supreme Court said that compelled disclosures are subject to lower scrutiny only if they are "reasonably related" to a specific interest: "preventing deception of consumers." 471 U.S. at 651. In later opinions, the Supreme Court confirmed that view of *Zauderer*. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010) (applying *Zauderer* because, as "in that case, [the] required disclosures are intended to combat the problem of inherently misleading commercial advertisements"); *Ibanez v. Fla. Dep't of Bus. & Prof'l Reg.*, 512 U.S. 136, 146–49 (1994) (applying intermediate scrutiny, rather than *Zauderer*, to compelled disclaimer directed at non-misleading speech).

The Supreme Court has never suggested that *Zauderer* applies in other contexts. And a majority of the courts of appeals acknowledge this limit on *Zauderer*. *See Dwyer v. Cappell*, 762 F.3d 275, 282–83 (3d Cir. 2014) (holding that a compelled disclosure failed *Zauderer* because it "[was] not reasonably related to preventing consumer deception and [was] unduly burdensome"); *Greater Baltimore Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council of Baltimore*, 721 F.3d 264, 283 & n.8 (4th Cir. 2013) (holding that *Zauderer* applies only to "[d]isclosure requirements aimed at misleading commercial speech"); *Test Masters Educ. Servs., Inc. v. Robin Singh Educ. Servs., Inc.*, 799 F.3d 437, 453 (5th Cir. 2015) (holding that *Zauderer* applies only when compelled disclosures are "directed at deceptive or misleading commercial speech"), *rev'd in part on other grounds*, 2015 WL 13768849; *ECM BioFilms, Inc. v. FTC*, 851 F.3d 599, 616 (6th Cir. 2017) (holding that disclosure requirements "must be reasonably related to the [government's] interest in preventing deception of consumers" (quotation marks omitted)); *1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1062 (8th Cir. 2014) (applying the *Zauderer* standard only because the advertisements at issue were "inherently misleading on their face"); *Entm't Software*, 469 F.3d at 652 ("The Court has allowed states to require the inclusion of purely factual and uncontroversial information as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." (ellipsis and quotation marks omitted)); *United States v. Wenger*, 427 F.3d 840, 849 (10th Cir. 2005) (explaining that *Zauderer* "eases the burden of meeting the *Central Hudson* test" by "presum[ing] that the government's interest in preventing consumer deception is substantial").

The graphic-warnings requirement and the proposed rule fail to satisfy this test. Neither Congress nor FDA has suggested that graphic warnings are needed to combat "inherently misleading commercial advertisements." *Milavetz*, 559 U.S. at 250. And that is not surprising: federal law already prohibits tobacco product manufacturers from making false or misleading claims through cigarette packages or advertising. *See* 21 U.S.C. §§ 331(a), 387c(a)(1), (7). Instead of preventing consumer *deception*, FDA says that it wants to "promote greater public

because the public accurately perceives the danger of smoking (and indeed may even overestimate that danger).

1. Americans are "already surrounded by many high-quality sources of information regarding smoking." Klick Report ¶ 5.3. For decades, Congress has required that cigarette manufacturers display warning labels that inform the public that cigarette smoking can cause serious diseases and harm one's health. In 1965, Congress mandated that cigarette packages include the following warning: "CAUTION: Cigarette Smoking May Be Hazardous to Your Health." Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282, 283 (1965). In 1969, Congress adopted a new warning: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87, 88 (1970). In Congress's view, this warning fully advised the public about the risk of smoking; thus, Congress provided that "[n]o statement relating to smoking and health, other than [this warning], shall be required on any cigarette package." *Id.* at 88. And in 1984, Congress required that all packaging and advertising include a series of rotating warnings that covered a variety of smoking risks:

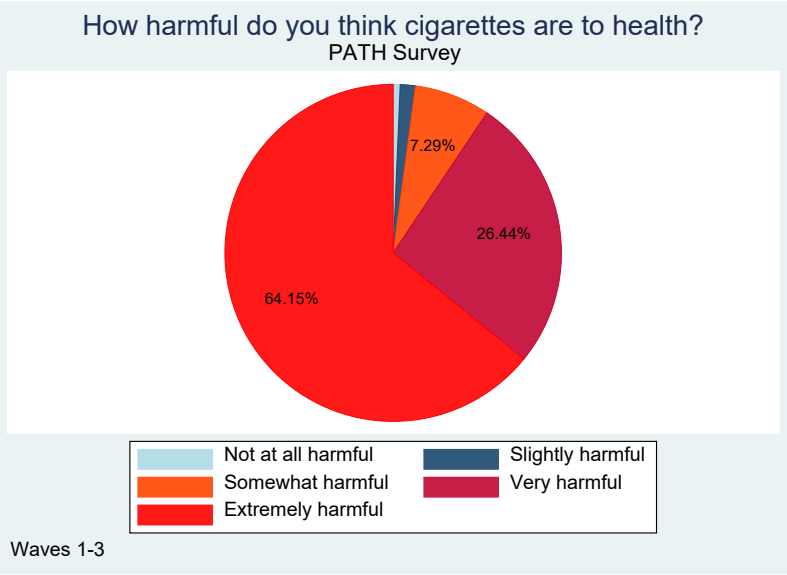
- "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.
- "SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
- "SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.
- "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide."

Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200, 2201–02 (1984). These warnings likewise preempted all other warnings. *See* 15 U.S.C. § 1334 (1988).

In addition to warning labels, the public has received information about the risks of cigarettes from many other sources. Since 1964, the Surgeon General has issued thirty-three reports about the health risks of smoking. Klick Report ¶ 5.6. Federal agencies such as the CDC and FDA have run public-education campaigns. *Id.*; Steenkamp Report § 3.2. State and local entities have done likewise. Klick Report ¶ 5.7. People also receive "substantial information regarding smoking from their doctors and other health professionals." *Id.* ¶ 5.9. "Public health organizations, including the American Cancer Society, the American Heart Association, and the American Lung Association, have also communicated smoking-related risks to consumers in many media, including broadcast media campaigns, pamphlet, and advertisements." *Id.* ¶ 5.10 (footnotes omitted). "[I]nsurance companies invest significant resources in educating their customers about the dangers of smoking in addition to providing support for cessation." *Id.* ¶ 5.10. And schools educate minors about the risks of smoking. *See* CDC, *Guidelines for School Health Programs to Prevent Tobacco Use and Addiction* (1994), https://tinyurl.com/y53dmhqf; FDA's Center for Tobacco Products, *Prevention Through Public Education* (Sept. 24, 2019) ("Campaign ads and other prevention resources are strategically placed where teens spend the majority of their time,

both online and in school. FDA also teamed up with Scholastic to create curriculum about e-cigarettes for high school teachers.").

2. As a result of these warning labels and public-health campaigns, the public already understands that smoking cigarettes is harmful. PATH data show that 99.5% of individuals believe that cigarette smoking is harmful to health, with 91% believing that it is "very or extremely harmful," 7% believing it is "somewhat harmful," and 1.5% believing it is "slightly harmful." Klick Report ¶ 5.20. Put differently, only 0.5% of people believe that smoking is *not* harmful at all, and only 1.5% believe it is "slightly harmful."



In addition, from 2002 to 2018, Gallup polls found that 81.5% of respondents believe that smoking is very harmful, and another 14% believe it is somewhat harmful. *Id.* ¶ 5.26.

It would be difficult, if not impossible, to improve these numbers. Experts generally agree that, "[a]s a practical matter, getting to awareness levels above 80 or 90 percent is unrealistic." *Id.* ¶ 5.17. Indeed, more people know that smoking is harmful to health than know that the Earth revolves around the sun (74%), or where the United States is on a map (94%). *See* Nat'l Sci. Found., *Science and Engineering Indicators* 7-23 (2014), https://tinyurl.com/y3ojlwu4; Nat'l Geographic Educ. Found., *2006 Geographic Literacy Study* 26 (2006), https://tinyurl.com/y35yaj2t. Thus, the data described above show that the public universally understands that smoking is harmful.

Data also show that the public is universally aware of the major risks of cigarettes. For example, PATH data show that 94% of individuals believe that smoking causes lung cancer, 94% believe that smoking causes lung disease, and 88% believe that smoking causes heart disease. *See* Klick Report ¶¶ 5.41, 5.43, 5.48.

3. In the proposed rule, FDA acknowledges that the public universally understands the major risks of smoking. For example, the proposed rule does not include warnings that "Cigarettes are addictive," that "Smoking can kill you," or that "Quitting smoking now greatly reduces serious risks to your health," because the public already knows those things. *See* 84 Fed. Reg. at 42,767

n.5, 42,772. The proposed rule also does not include a warning about lung cancer—presumably because FDA believes that the public already knows about that risk.

Moreover, FDA expressly concedes that the public knows about the risks described in the nine warning statements required by the Tobacco Control Act. FDA acknowledges that there are "recent studies conducted in the United States that failed to find an effect of pictorial cigarette warnings on increasing health beliefs about the negative effects of smoking." 84 Fed. Reg. at 42,763 (citing Brewer et al. 2018, Byrne et al. 2017, Niederdeppe et al. 2019, Skurka et al. 2018). FDA attributes that failure to the "high pre-existing level of knowledge of the specific health consequences described in the warnings tested in those studies." *Id.* at 42,764. Importantly, those studies tested all nine of the Act's warning statements—which means that, in FDA's view, the public has such a "high pre-existing level of knowledge" about the risks described in the Act's warning statements that graphic warnings cannot increase the public's knowledge any further. FDA has therefore conceded that that the public universally knows that "Tobacco smoke can harm your children," "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," and "Tobacco smoke causes fatal lung disease in nonsmokers." *See also* 84 Fed. Reg. at 42,767–68 (acknowledging that, in FDA's first consumer research study, "relatively few participants reported that the content of the TCA statements was new information").

Not only does the public understand these risks, the public actually *overestimates* many of them. For example, in one study, smokers and non-smokers alike "substantially over-estimated the lung cancer rate of smokers, as well as the contribution of smoking to over-all mortality and expected losses in lifespan." Klick Report ¶ 5.71. Thus, FDA cannot assert an interest in increasing the public's understanding of these risks.

4. FDA tries to sidestep this problem by adopting warnings that allegedly focus on "less-known health consequences of smoking." 84 Fed. Reg at 42,755. But the proposed rule fails to demonstrate that the public does not already understand these risks.

Once again, PATH data and other surveys show that the public is universally aware of almost all of the risks that FDA describes as "less-known." For example:

- 94% of people believe that smoking causes lung disease. Klick Report ¶ 5.48.
- In 2017, 93% of people listed tobacco as a risk factor for cancer. *Id.* ¶ 5.50.
- 91% of people believe that cigarette smoke can harm your children. *Id.* ¶ 5.59.
- 88% of people believe that smoking causes heart disease and 80% believe that smoking causes stroke. *Id.* ¶¶ 5.43, 5.45.
- 86% of people agreed that smoking causes harm to fetuses. *Id.* ¶ 5.58.

- 83% of people believe that second-hand smoke causes lung disease in non-smokers. *Id.* ¶ 5.60.

- 82% of people believe that smoking causes circulation problems. *Id.* ¶ 5.47.

Surprisingly, FDA does little to demonstrate that the public does not already know about these risks of smoking. In the proposed rule, FDA asserts that "findings in the scientific literature demonstrate that the U.S. public—including youth and adults, smokers and nonsmokers—holds misperceptions about the health risks caused by smoking." 84 Fed. Reg. at 42,756. But FDA's citations do not back up that claim. For example, FDA repeatedly relies on studies that are nearly or more than a decade old and say *nothing* about the current state of the public's knowledge. *See id.* at 42,761 (citing five articles based on 2001 studies, one article based on a 2002 study, one article based on a 2004 study, one article based on a 2008 study, and three articles based on 2010 studies). FDA also repeatedly relies on studies of the populations of other countries, such as Canada, China, Singapore, Scotland and the United Kingdom. *See id.* And FDA relies on multiple studies that discuss health risks (such as cervical cancer, infertility, kidney cancer, and osteoporosis) that are not addressed in the proposed warnings. *See id.* None of these studies shed any light on the relevant question: what does the U.S. population currently know about the health risks identified in the proposed warnings?

FDA relies on only a handful of studies that address that question. And several of those studies actually show that the public *does* understand the health risks identified in the proposed warnings. For example, FDA relies on a 2015 study showing that 94.6% of people know that smoking causes throat cancer, 83.3% of people know that smoking causes oral cancer, 93.1% of people know that smoking causes mouth cancer, 82.1% of people know that smoking causes esophagus cancer, and 60.6% of people know that smoking causes lip cancer. *See id.* That study therefore undermines, rather than supports, FDA's assertion that people do not understand that smoking causes head and neck cancer. *See also id.* (relying on a 2010 study showing that "[p]articipants knew about the risk of [low birth weight] and premature birth, supporting previous research on the topic").

Moreover, FDA cannot rely on its consumer research studies to demonstrate that the public does not know about these risks. As an initial matter, these surveys suffer from methodological problems that prevent FDA from relying on them. *See infra* pp. 41–42. In addition, these surveys lack virtually any relevant information about the public's knowledge. Those surveys asked respondents (among other things) whether FDA's proposed graphic warnings contained "new information" and whether respondents "learned something" from the warnings. 84 Fed. Reg. at 42,771. But these "new information" and "self-reported learning" measurements are virtually meaningless. Both questions are dripping with social-desirability bias: FDA's surveys plainly convey to respondents that they are supposed to say that the warnings contain "new information" and that the respondents "learned something." This is clearly illustrated by the results that FDA got when it asked these questions about the 35-year-old, universally known Surgeon General's warnings: 27.9% of people said that they contained "new information" and the "mean rating of self-reported learning … was 3.02" on a scale of 1 (learned nothing) to 7 (learned very much). Such high results demonstrate that FDA's questions are irredeemably flawed.

In addition, FDA's first consumer research study calls into doubt whether the proposed warnings actually convey any new information. As explained above, FDA concedes that the Tobacco Control Act's warnings cannot meaningfully increase the public's understanding about the risks of smoking because "the public already has a high pre-existing level of knowledge" about those risks. *See supra* p. 15. And FDA's first consumer research study suggests that the proposed warnings fare little better. That survey analyzed whether respondents thought that FDA's proposed textual warnings were more "informative" than the Tobacco Control Act's textual warnings. Only two of the proposed textual warnings passed that test. *See* Study 1 Results Report at 3-11. If the Act's textual warnings are universally understood (as FDA concedes), and the proposed textual warnings are not any more informative, it stands to reason that the proposed textual warnings are likewise universally understood.

Tellingly, FDA is silent about other measures that could show whether the public understands these risks. For example, FDA could have relied on the PATH data discussed above: after all, the PATH survey was "started explicitly to inform the FDA's regulatory decisions and actions with respect to smoking." Klick Report ¶ 5.18. But FDA ignored that evidence, which shows that the public universally understands almost all of these risks. In addition, at the beginning of FDA's second consumer research study, the Agency asked respondents whether smoking caused the diseases that are mentioned in the warnings. But FDA has not released that data—perhaps because the data show that FDA was trying to solve a hypothetical problem.

5. Most importantly, FDA effectively *concedes* that the public already knows about many of the risks identified in the proposed warnings.

To begin, take the two textual warning statements that FDA retained from the Tobacco Control Act: "Tobacco smoke can harm your children" and "Tobacco smoke causes fatal lung disease in nonsmokers." 84 Fed. Reg. at 42,797. As explained above, FDA has conceded that "the public already has a high pre-existing level of knowledge of the[se] specific health consequences," 84 Fed. Reg. at 42,764, and that showing these warnings to people will not increase their understanding. *See supra* p. 15. Given that everyone "already know[s]" this information, these warnings are unjustified. *NIFLA*, 138 S. Ct. at 2377.

In addition, several of the proposed warnings do not convey any relevant information beyond what the Tobacco Control Act's warnings conveyed. For example, one of the Act's warnings says that "Cigarettes cause strokes and heart disease." 15 U.S.C. § 1333(a)(1). FDA's proposed warning repeats virtually the same information: "Smoking can cause heart disease and strokes by clogging arteries." 84 Fed. Reg. at 42,797. The proposed warning conveys the exact same information about the *risk* of smoking cigarettes (that it can cause strokes and heart disease) and then conveys a granular piece of information about how the risk operates (by clogging arteries). Even if this disease *mechanism* is new information to some people, FDA has not shown (and cannot show) that adding this granular piece of information affects the public's understanding about the *risks* of smoking.

As another example, one of the Act's warnings says that that "Cigarettes cause fatal lung disease." 15 U.S.C. § 1333(a)(1). Again, FDA's proposed warning repeats virtually the same information: "Smoking causes COPD, a lung disease that can be fatal." 84 Fed. Reg. at 42,797. As before, the proposed warning does not convey any additional information about the *risk* of smoking

cigarettes; it simply names the "fatal lung disease" that is described in both warnings. Moreover, it is not clear that much of the public will know what COPD is, thus making the proposed warning unnecessarily complex and less meaningful. The same analysis largely applies to the proposed warning "Smoking causes head and neck cancer," which conveys little beyond the Act's warning "Cigarettes cause cancer," and the proposed warning "Smoking during pregnancy stunts fetal growth," which conveys little beyond "Smoking during pregnancy can harm your baby." *Compare* 15 U.S.C. § 1333(a)(1), *with* 84 Fed. Reg. at 42,797.

In short, the evidence shows that the public "already knows" about the major risks of smoking *and* many of the risks identified in the proposed warnings. *NIFLA*, 138 S. Ct. at 2377. FDA nevertheless insists that the public needs to be warned about these risks, and graphic warnings are the only way to do so. That is a solution in search of a problem, and it is "unjustified" under *Zauderer*. *See NIFLA*, 138 S. Ct. at 2377.

(b) Even if the public did not understand these risks, FDA has not shown that graphic warnings would increase the public's understanding.

The evidence demonstrates that FDA has not shown that the public lacks relevant information about the risks of smoking. But even if FDA could make such a showing, the Agency has not shown that graphic warnings would address that problem.

1. As explained above, graphic warnings evoke negative emotions such as fear, shame, and disgust. *See supra* Section I.B.1. But the "empirical evidence on the use of emotional appeals in warnings is mixed at best." Klick Report ¶ 5.81. As Dr. Martin explains, "[n]euroscience supports the [conclusion] that smokers have a strong tendency to avoid high-threat messages." Martin Report at 5. Dr. Martin's clinical experience confirms that fact: "Through additional interviews, we found that the smokers were already aware of those risks and chose to avoid thinking about them to the point of rejecting, and becoming irritated by, the message as well as the messenger." *Id.* at 6.

Professor Joannes Evangelista Steenkamp, who is an expert in marketing communications, agrees with Dr. Martin. As Professor Steenkamp explains, a "negative emotion like fear" can undermine a message's effectiveness. Steenkamp Report at 17. A high level of fear "produces inhibiting effects," which may cause the audience to "emotionally block the message by tuning out, perceiving it selectively, or denying its arguments outright." *Id.* Thus, "[r]esearch has shown that anti-smoking messages and graphic health warnings using high levels of fear were ineffective because they led to defensive tendencies such as message avoidance and interfered with the processing of recommended solutions." *Id.*

Because of these dynamics, multiple studies have concluded that graphic warnings do not change people's beliefs about the harms of smoking. *See, e.g.*, Brewer et al. 2018, at 238; Byrne et al. 2017, at 313; Byrne et al. 2015, at 686–88, 690; Niederdeppe et al. 2019, at 47; Skurka et al. 2018, at 863; Sussenbach et al. 2013, at 1202.

2. FDA tries to demonstrate that the proposed warnings would increase the public's knowledge by relying on its second consumer research study. FDA begins by arguing that the

(1977) (invalidating ban on house "for sale" signs where the alternative avenues of speech existed only "in theory").

d. In contrast to the burdensome graphic-warnings requirement, Congress and FDA have many less-restrictive alternatives for achieving their objectives. For example, they could (a) change the text of the existing warnings, (b) change the size and placement of those warnings, or (c) adopt graphic warnings that have a less-intrusive size and placement or less-provocative content. Congress and FDA could require that each cigarette package include an insert that provides information about various health risks. *See* James F. Thrasher et al., *Cigarette Package Inserts Can Promote Efficacy Beliefs and Sustained Smoking Cessation Attempts: A Longitudinal Assessment of an Innovative Policy in Canada*, 88 Prev. Med. 59 (2016). Congress and FDA could run a public-education campaign about the risks of smoking. *See NIFLA*, 138 S. Ct. at 2376 (holding that a compelled disclosure did not survive even intermediate scrutiny because, among other things, the state could itself "inform low-income women about its services" "with a public-information campaign"). And if Congress and FDA wanted to reduce smoking, they could try giving people accurate information about potentially less-harmful tobacco products and urging them to switch, or giving smokers cessation aids, such as a quitting hotline or free nicotine replacement products. *See* Andrew Whitney, *Michigan Gives Out Free Nicotine Patches, Gum As Part Of Stop Smoking Campaign*, The Heartland Institute (July 24, 2019), https://tinyurl.com/y2atp9dd.

FDA has a constitutional obligation to try all of these less-restrictive alternatives. But two of these options stand out: new textual warnings (without graphic images) and public-education campaigns.

New Textual Warnings. First, adopting new textual warnings without graphic images would almost certainly achieve FDA's informational goal. Since 1965, Congress has required manufacturers to display warnings on all cigarette packages. In part because of those warnings, the public already understands that smoking cigarettes is harmful and knows about the major risks of smoking. *See supra* pp. 14–15. There is no reason to believe that new textual warnings could not be effective.

In addition, the evidence suggests that new textual warnings would be at least as effective as graphic warnings. A recent survey compared the proposed graphic warnings to several different less-restrictive alternatives, such as text-only warnings on the side of the pack. Iyengar Report ¶ 20. That survey found very few statistically significant differences between FDA's proposed warnings and those less-restrictive alternatives regarding the amount of new information conveyed by the warnings and respondents' beliefs about the risks of smoking after viewing the warnings. *Id.* ¶¶ 23–28. For example, for the new-information measurement, there were no statistically significant differences between FDA's proposed warnings and text-only warnings on the side of the pack, and for the health-beliefs measurement, there were no statistically significant differences between FDA's proposed warnings and text-and-graphics warnings on the side of the pack. *See id.* ¶¶ 24, 27. Other studies on less-restrictive alternatives have reached similar conclusions. Klick Report ¶ 7.12; *see also* Glock et al. 2013, at 259 (finding "no difference in risk perception" between groups who saw graphic warnings and textual warnings); Klein et al. 2015, at 182 (finding that "increasing the size of graphic warnings from 20% to 33% of an advertisement's space" had no effect on "smokers' attention" or "repeat views"); Pepper et al. 2013, at 4 (finding that "warnings

with these graphic images did not discourage adolescent males from wanting to smoke more than text-only warnings"). Indeed, new textual warnings might actually be *more* effective than graphic warnings because they do not rely on the type of fear-based appeals that cause some people to "reject[] the message as well as the messenger." Martin Report at 6; *see also supra* Section I.B.6(b).

In the proposed rule, FDA suggests that the Surgeon General's warnings are inadequate because of their "small size," "lack of an image," and "unchanged content." 84 Fed. Reg. at 42,759. But the evidence strongly suggests that any problems with the Surgeon General's warnings stem from the "unchanged content," rather than their size or lack of images. As FDA repeatedly notes, these warnings have not changed in 35 years. *See* 84 Fed Reg. at 42,756, 42,759, 42,760, 42,766. What's more, FDA explains that daily smokers see these warnings "over 5,100 times per year." *Id.* at 42,764, 42,759. And as explained above, the public already knows the information in those warnings. It is no great mystery, therefore, that people often do not read or think about the warnings.

In 2018, RAIS urged FDA to test several less-restrictive alternatives to see whether they would be as effective as graphic warnings. For example, RAIS suggested that FDA "show one group of participants a package with the current Surgeon General's warnings, show 16 groups a package with the new textual warnings, and show 16 more groups a package with the new textual warnings and graphic images." *See* RAIS Comments, Docket No. FDA-2018-N-3552, at 4 (Nov. 16, 2018). This type of study would have "allow[ed] FDA to determine how much the graphic images contribute, if at all, to FDA's stated goal" of conveying information to the public. *Id.* But FDA flatly refused to test this—or any other—less-restrictive alternative. Given FDA's refusal to test these alternatives, FDA has no basis whatsoever to conclude that any "new information" conveyed by, or any "self-reported learning" caused by, the proposed warning is attributable to the graphic images, rather than the textual warning statements.

Public-Education Campaign. There is also strong evidence that an FDA-run public-education campaign would be significantly more effective than the proposed graphic warnings.

Over the past several decades, FDA has run multiple public-education campaigns to educate the public about the risks of smoking cigarettes. Between 2009 and 2014, FDA spent more than $500 million on such campaigns. U.S. Gov't Accountability Office, No. 14-561, *Most FDA Spending Funded Public Education, Regulatory Science, and Compliance and Enforcement Activities* at 16–17 (June 2014), https://tinyurl.com/y93gktex. And since 2014, FDA has run several different campaigns, including *The Real Cost*, *Fresh Empire*, *This Free Life*, and *Every Try Counts*.

These campaigns have several advantages over graphic warnings. These campaigns can use many different communication channels, such as television, radio, websites, and social media, that allow the speaker to convey more information than FDA can convey through graphic warnings. Steenkamp Report § 4.4. These campaigns can also be changed more quickly than graphic warnings, which allows the speaker to convey more current information. Klick Report ¶ 5.14. And these campaigns can target particular groups by using different messages and different communication channels, rather than using a "one-size-fits-all message" like graphic warnings. Steenkamp Report at § 3.1.

FDA has conceded that public-education campaigns have many of these benefits. For example, in the context of its ongoing *The Real Cost* campaign regarding the dangers of e-cigarettes, FDA has boasted about its ability to "ensure [that its] messages are reaching the intended youth audience" by, among other methods, (1) running ads "on age-verified digital platforms such as YouTube, Spotify, Pandora, Facebook and Instagram," (2) "using location-targeted advertising around high schools nationwide," and (3) placing e-cigarette prevention content on educational platforms that are typically accessed by students during the school day." FDA News Release (Sept. 18, 2018), https://tinyurl.com/y2adoe6w; *see also* FDA News Release (July 22, 2019), https://tinyurl.com/yxnkj52k (explaining that the *Real Cost* campaign's new ads would "run on television networks such as TeenNick, CW, ESPN and MTV, as well as music streaming sites, social media networks and other teen-focused media channels"); *id.* (explaining that the *Real Cost* campaign "has generated nearly 2 billion teen views in 9.5 months," and has received "more than 578,000 likes, 89,000 shares, and 31,000 comments" on social media platforms).

FDA has also suggested that public-education campaigns can reduce smoking. Indeed, the same week that FDA issued the proposed rule, FDA touted the *Real Cost* campaign as "highly successful" and as "yielding tremendous results." Norman E. Sharpless, *Press Announcement* (Aug. 20, 2019), https://tinyurl.com/y3kmouoa. Specifically, FDA alleged that the *Real Cost* campaign had "prevented up to 587,000 youth nationwide from initiating smoking between the campaign's launch in February 2014 and November 2016, half of whom might have gone on to become established smokers." *Id.*; *see also* Duke et al. 2019. And in late September 2019, FDA boasted about a "series of groundbreaking public education initiatives to prevent young people from ever starting to use tobacco and to help addicted smokers quit." FDA's Center for Tobacco Products, *Prevention Through Public Education* (Sept. 24, 2019), https://tinyurl.com/y6c6veez.

In sum, the evidence strongly suggests that these less-restrictive alternatives would achieve FDA's informational objective. For the past several decades, the government has used a combination of textual warnings (without graphic images) and public-education campaigns to tell the public about the major risks of smoking, such as lung cancer. *See supra* Section I.B.6(a). Because of those efforts, the public *universally understands* those risks, and actually *overestimates* many of them. *See id.* There is no reason to believe that these less-restrictive alternatives would be any less effective here.

e. The proposed rule does not meaningfully discuss the burdens that graphic warnings place on manufacturers or FDA's less-restrictive alternatives. Instead, FDA cites *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), for the proposition that the Tobacco Control Act's graphic-warnings requirement is "not unduly burdensome because a manufacturer has the ability to convey other information of its choosing in the remaining space available." 84 Fed. Reg. at 42,778 (citing *Disc. Tobacco*, 674 F.3d at 530–31). But FDA fails to acknowledge that it cites the *dissenting opinion* for that proposition.

FDA likewise fails to acknowledge that it has the burden of proving that less-restrictive alternatives are not sufficiently effective. *NIFLA*, 138 S. Ct. at 2376 ("California argues that it has already tried an advertising campaign, and that many women who are eligible for publicly-funded healthcare have not enrolled. But California has identified no evidence to that effect."); *Philip Morris*, 566 F.3d at 1143 ("Although the standard for assessing burdens on commercial speech has

III. THE PROPOSED RULE DOES NOT COMPLY WITH THE ADMINISTRATIVE PROCEDURE ACT.

The proposed rule also violates the Administrative Procedure Act in several respects. First, FDA improperly relied on an inadequate cost-benefit analysis (which, among other problems, completely fails to quantify the rule's purported benefits). Second, FDA failed to articulate a rational justification for the rule. Third, FDA failed to consider reasonable alternatives. And finally, FDA has failed to give the public a meaningful opportunity to comment, and instead has withheld information from the public at every turn.

Some of these errors may have resulted from a court order requiring FDA to release its proposed rule far earlier than FDA had hoped. Memorandum and Order at 5, *American Academy of Pediatrics et al. v. FDA*, No. 1:16-cv-11985-IT (Mar. 5, 2019). The same court order also requires FDA to publish its final rule on an expedited timeline; as a result, FDA will not have the opportunity to meaningfully respond to the comments it receives.

A. The proposed rule's cost-benefit analysis is irrational.

Where an agency "decides to rely on a cost-benefit analysis as part of its rulemaking," that analysis must itself be reasonable. *National Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) (noting that the court would not "tolerate rules based on arbitrary and capricious cost-benefit analyses" (quotation marks omitted)); *Idaho Conservation League v. Wheeler*, 940 F.3d 494, 507 (D.C. Cir. 2019) ("[W]hen an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." (quotation marks omitted)); *see also, e.g., Business Roundtable v. S.E.C.*, 647 F.3d 1144, 1148 (D.C. Cir. 2011) (noting that an agency had acted arbitrarily and capriciously in failing "adequately to assess the economic effects of a new rule"). The purported cost-benefit analysis accompanying the proposed rule does not come close to satisfying this requirement; to the contrary, it is fundamentally inadequate in several respects.

The failures of this cost-benefit analysis are especially notable in light of FDA's experience with the original graphic-warnings rule. In the regulatory impact analysis that accompanied that rule, FDA attempted to quantify the reduction in smoking that the rule would supposedly produce. As the D.C. Circuit noted, however, the result of that analysis was that the reduction would be *de minimis*, and could not be statistically distinguished from zero. *R.J. Reynolds*, 696 F.3d at 1219–20. The agency's cost-benefit analysis, in short, did not amount to even "a shred of evidence—much less the 'substantial evidence' required by the APA—showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." *Id.* at 1219. One might have expected that, mindful of this rebuke, the Agency would be especially careful this time around to provide a rigorous and thorough analysis quantifying the proposed rule's purported benefits. Remarkably, FDA did precisely the opposite and *declined to attempt to quantify those benefits at all*. It is hard to interpret this decision as anything other than a tacit admission that those benefits simply do not exist.

1. At a minimum, a cost-benefit analysis must quantify both the costs and the benefits of the proposed regulation. Klick Report ¶ 8.5. Notably, the preliminary regulatory impact analysis that accompanies the proposed rule fails to meet even that low bar. Instead, it expressly forgoes

any effort to quantify the proposed rule's benefits. It acknowledges that "there is a high level of uncertainty around quantitative economic benefits" and therefore chooses to "describe them qualitatively." PRIA at 2. As a result, no direct comparison is possible between the rule's benefits and its costs. Instead, FDA is forced to rely on a "break-even calculation," which concludes that the rule will be beneficial on net "[i]f the information provided by the cigarette health warning on each cigarette package were valued at about $0.01." *Id.* at 37–38. This is not helpful in evaluating the rule, as FDA provides no reason to believe that the informational benefit *is* worth $0.01 or more per pack. Indeed, as Professor Klick shows, the per-pack benefits could be less than zero even before the costs of the regulation are taken into account. Klick Report ¶ 8.6. In short, FDA's cost-benefit analysis says *nothing* about whether the rule's benefits exceed its costs, and indeed about whether the benefits exist at all—let alone whether they could possibly be sufficient to satisfy the demands of the First Amendment.

Break-even analyses of this sort have been criticized as an unproven tool which may not improve the rationality of regulatory analyses. *Id.* ¶ 8.7. A key weakness of break-even analyses, which is on full display here, is that they are overly dependent on framing effects. *Id.* By choosing to frame the break-even benefit on a per-pack basis, FDA was able to claim that the threshold for the rule to become beneficial was seemingly low—just $0.01 per pack. But if FDA had framed the break-even benefit on a per-smoker basis, the required benefit would be much larger—perhaps $400 per smoker. *Id.* That threshold might appear much harder to satisfy, even though it is simply another way of describing the same required aggregate benefit. This further illustrates the irrationality of FDA's approach.

FDA's failure to quantify the rule's benefits is particularly egregious in light of the fact that the benefits are almost certainly small or nonexistent. The only interest FDA asserts is in promoting greater public understanding of the dangers of smoking. But as explained above, the rule will not meaningfully contribute to that goal, as the dangers of smoking are already widely understood. *See supra* Section I.B.6(a). And even if the rule did impart some information to consumers, FDA would have no basis for asserting that the information would be valuable. *See supra* Section I.B.6(b). Ordinarily, in economic analysis, the value of information is estimated by measuring the effect of that information on behavior. Klick Report ¶ 8.5. Here, however, FDA does not claim that the warnings would cause any change in behavior (and, as discussed above, the warnings in fact would not cause any reduction in smoking). As such, it is "difficult to understand" how the information conveyed by the warnings could be valuable. *Id.* Alternatively, FDA might have attempted to estimate the value of the information based on willingness to pay. But those estimates would likely have been negligible because the information is freely and easily accessible from a variety of sources, including government websites. *Id.*

Notably, in other contexts, FDA is quite willing to quantify the benefits of its programs. For example, it recently asserted that its *Real Cost* campaign had "prevented up to 587,000 youth nationwide from initiating smoking," and would purportedly "save more than $53 billion for youth, their families and society at large by reducing smoking-related costs like early loss of life, costly medical care, lost wages, lower productivity and increased disability." Norman E. Sharpless, *Press Announcement* (Aug. 20, 2019), https://tinyurl.com/y3kmouoa.

2. Moreover, while FDA *does* purport to quantify the rule's costs, it underestimates those costs by entirely overlooking several categories of costs. First, FDA fails to take into account the

cost of RAIS's lost ability to use its packaging to communicate with consumers. FDA recognizes that requiring manufacturers to devote 20% of their advertising space to graphic warnings would impose costs. PRIA at 34. But FDA fails to recognize that requiring manufacturers to devote 50% of their packaging space to graphic warnings would also impose costs. *See* Klick Report ¶ 8.8. FDA fails to account for those costs, even though FDA acknowledges that advertising is very important to cigarette companies. *See* 84 Fed. Reg. at 42,759. In addition, FDA ignores the psychic costs to consumers who prefer the look of the original pack. Klick Report ¶¶ 8.9–8.10.

In sum, the cost-benefit analysis supporting the proposed rule is both inadequate and irrational. FDA's reliance on it is arbitrary and capricious under the APA.

B. FDA has failed to articulate a rational explanation for the proposed rule.

Under the APA, a rule is arbitrary and capricious if the agency fails to "articulate a satisfactory explanation for [the rule] including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983) (quotation marks omitted). Here, FDA has not articulated a rational justification for the proposed rule.

1. FDA claims that the proposed rule will increase consumer understanding of the risks of smoking. But as explained above, the public already overwhelmingly understands that smoking cigarettes can harm one's health, and in any event the proposed warnings would not affect the public's assessment of the hazards of smoking. FDA fails to account for those facts.

More generally, FDA relies on studies that are deeply flawed. Klick Report ¶ 8.4. For example, its first quantitative study did not consider a representative sample of the U.S. population. The Office of Management and Budget granted only a limited approval of that study and noted that, "[d]ue to the study design, convenience sampling methodology, and methods of analyses—significant limitations exist with regard to the generalizability of results from this study." OMB, *Notice of Office of Management and Budget Action, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings, Ref. No. 201708-0910-011* (Jan. 29, 2018), https://tinyurl.com/ybwk7ptv. "Because of these limitations, the relationship between treatment and outcomes [that FDA] find[s] in [its] study *may not generalize to the broader U.S. population*." *Id.* (emphasis added). Thus, FDA had to "confirm[] that all such limitations inherent in the study design and methodology will be communicated in all reports, presentations, and policy documents." *Id.* Accordingly, FDA now acknowledges that the survey for this study "used a convenience sample rather than a probability sample, and the results are not nationally representative." Study 1 Results Report at 4-4.

The second quantitative study also suffered from serious problems. Klick Report ¶ 8.4. As RAIS explained in its comments, this study (1) had a small sample size, (2) suffered from selection bias, (3) asked questions that created a serious risk of bias, (4) failed to adequately mimic real-world conditions, (5) lacked meaningful pretesting, and (6) failed to correct for social-desirability bias. RAIS Comment, Docket No. FDA-2018-N-3552 (Nov. 16, 2018); *see* Robert Hornik, *Proposal for an Administrative Supplement to a Research Grant from the National Institutes of Health* (Oct. 21, 2011) (attached as Exhibit M) ("Most current research supporting GWL choice involved single exposures to graphics and evaluation of responses. In contrast, most real life

Exhibit C

STATEMENT OF JONATHAN KLICK, PH.D., J.D.

U.S. FOOD AND DRUG ADMINISTRATION

DOCKET NO. FDA-2019-N-3065

("REQUIRED WARNINGS FOR CIGARETTE PACKAGES & ADVERTISEMENTS")

1. SCOPE OF ASSIGNMENT

1.1 I have been asked to provide comments in response to the Food and Drug Administration ("**FDA**") proposed rule requiring color graphics depicting the health consequences of smoking on cigarette packs and in cigarette advertisements. (See FDA Proposal, Docket No. FDA-2019-N-3065). My comments also respond to the FDA's preliminary regulatory impact assessment and qualitative studies of graphic warnings and corresponding analyses ("**FDA Studies**").

1.2 I appreciate the opportunity to provide these comments as the FDA Proposal and FDA Studies pertain to subjects that I have considered and researched.

1.3 I am providing these comments at the request of RAI Services Company ("**RAIS**"), and I have been compensated for the time I have spent in doing so.[1]

2. INTRODUCTION

2.1 After a brief description of my professional qualifications and relevant experience, I address the following key points:

- 2.1.1 The function and efficacy of warnings;
- 2.1.2 The proposed FDA warnings will not meaningfully increase consumer understanding;
- 2.1.3 The available data on smoking prevalence does not support the efficacy of the proposed FDA warnings in reducing smoking;
- 2.1.4 The literature supporting graphic warnings is flawed and unreliable; and
- 2.1.5 The FDA's preliminary regulatory impact assessment is speculative and unreliable, as are the studies the FDA undertook in support of the impact assessment.

2.2 While my conclusions are apparent from the material that follows, I would like to make the following introductory remarks.

2.3 The Federal Government has a long history of requiring warnings on cigarette packages, dating back to the Federal Cigarette Labeling and Advertising Act of 1965, which mandated the inclusion of health warnings on cigarette packages. Warnings have continued to appear on cigarette packages since 1966, and Surgeon General warnings have appeared in all cigarette advertisements since 1972.

2.4 The current 15 U.S. Code § 1331 provides that "[i]t is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby— (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health."

2.5 In 1984, Congress mandated the following series of rotating warnings covering a variety of smoking risks, which have continued to be rotated on cigarette packages since 1985:

---

[1] None of my academic research has been funded or otherwise supported by the tobacco industry.

Table 1: Cigarette Warning Content Summaries

Warning Period	Warning Content
Cigarette warning, 1965	"Caution: Cigarette Smoking May Be Hazardous to Your Health"
Cigarette warning, 1969	"Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health"
Cigarette warning, 1984	1. "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy" 2. "SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health" 3. "SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight" 4. "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide."

5.6 Additionally, many other federal agencies have funded information campaigns,[10] and the Surgeon General has continued to issue reports about the health risks of smoking fairly regularly. A list of the Surgeon General reports addressing smoking and tobacco use is provided in Table 2 below:

Table 2: Surgeon General's Reports on Smoking

Year	Report
1964	Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service
1967	The Health Consequences of Smoking: A Public Health Service Review
1968	The Health Consequences of Smoking: 1968 Supplement to the 1967 Public Health Service Review
1969	The Health Consequences of Smoking: 1969 Supplement to the 1967 Public Health Service Review
1971	The Health Consequences of Smoking: A Report of the Surgeon General
1972	The Health Consequences of Smoking: A Report of the Surgeon General
1973	The Health Consequences of Smoking
1974	The Health Consequences of Smoking
1975	The Health Consequences of Smoking
1976	The Health Consequences of Smoking: Selected Chapters from 1971 through 1975
1978	The Health Consequences of Smoking, 1977 – 1978
1979	Smoking and Health: A Report of the Surgeon General
1980	The Health Consequences of Smoking for Women: A Report of the Surgeon General
1981	The Health Consequences of Smoking – The Changing Cigarette: A Report of the Surgeon General
1982	The Health Consequences of Smoking – Cancer: A Report of the Surgeon General
1983	The Health Consequences of Smoking – Cardiovascular Disease: A Report of the Surgeon General
1984	The Health Consequences of Smoking – Chronic Obstructive Lung Disease: A Report of the Surgeon General

[10] See, for example, the CDC's National Tobacco Education Campaign which has claimed great success https://www.cdc.gov/media/releases/2016/p0324-anti-smoking.html. The FDA's "Real Cost" campaign has likewise claimed success in educating youth about the dangers of smoking; see https://www.fda.gov/tobacco-products/real-cost-campaign/real-cost-cost-effective-approach.

Year	Report
1985	The Health Consequences of Smoking – Cancer and Chronic Lung Disease in the Workplace: A Report of the Surgeon General
1986	The Health Consequences of Involuntary Smoking: A Report of the Surgeon General
1988	The Health Consequences of Smoking – Nicotine Addiction: A Report of the Surgeon General
1989	Reducing the Health Consequences of Smoking – 25 Years of Progress: A Report of the Surgeon General
1990	The Health Benefits of Smoking Cessation: A Report of the Surgeon General
1992	Smoking and Health in the Americas: A Report of the Surgeon General
1994	Preventing Tobacco Use Among Young People: A Report of the Surgeon General
1998	Tobacco Use Among U.S. Racial/Ethnic Minority Groups
2000	Reducing Tobacco Use: A Report of the Surgeon General
2001	Women and Smoking: A Report of the Surgeon General
2004	The Health Consequences of Smoking: A Report of the Surgeon General
2006	The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General
2010	How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General
2012	Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General
2014	The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General
2016	E-Cigarette Use Among Youth and Young Adults.

5.7 Recent tobacco control research has also found that state and local spending on health communication has a significantly negative effect on actual cigarette sales.[11] These programs are constantly expanding and evolving, using innovative mixes of information and cessation support.[12]

5.8 Accordingly, altogether, the local, state, and federal governments provide substantial continually updated health information regarding the effects of smoking.

5.9 Beyond public information sources, individuals receive substantial information regarding smoking from their doctors and other health professionals. A 2016 Commonwealth Fund International Health Policy Survey asked smokers from 11 countries, including the United States "During the past two years have you and your doctor or other clinical staff at the place you usually go to for care talked about the health risks of smoking and ways to quit?" Of the 293 smokers from the U.S. who answered the question, 82 percent indicated that they had discussed the health effects of smoking with a medical professional during the past two years.[13] This rate was substantially higher than the 53 percent observed among the smokers from the other countries – all of which have more extensive cigarette warning label regimes than the one in force in the United States (Australia: 63 percent; Canada: 73 percent; New Zealand: 66 percent; United Kingdom 63 percent; Germany: 18 percent; Netherlands: 58

[11] John A. Tauras, Xin Xu, Jidong Huang, Brian King, S. Rene Lavinghouze, Karla S. Sneegas, and Frank J. Chaloupka (2018), "State tobacco control expenditures and tax paid cigarette sales," PLoS ONE 13(4): Table 3.

[12] See, for example, https://www1.nyc.gov/site/doh/about/press/pr2019/anti-smoking-media-campaign.page which discusses a 2019 New York City campaign that, in addition to increasing anti-smoking advertising in the city, provided free nicotine patches and lozenges for a limited time. On the other side of the country, Berkeley also provides cessation support to its residents, in addition to providing anti-smoking information https://www.cityofberkeley.info/Health_Human_Services/Public_Health/Tobacco_Prevention_Program.aspx.

[13] Commonwealth Fund, 2016 Commonwealth Fund International Health Policy Survey, survey question 31099599.00128 Cornell University Roper Center for Public Opinion Research iPoll.

percent; France: 52 percent; Norway: 33 percent; Sweden: 62 percent; Switzerland: 40 percent). The American Academy of Family Physicians notes that advice from a healthcare professional can double the quitting success rate of smokers.[14]

5.10 Public health organizations, including the American Cancer Society,[15] the American Heart Association,[16] and the American Lung Association,[17] have also communicated smoking-related risks to consumers in many media, including broadcast media campaigns, pamphlet, and advertisements. Some of these efforts involve innovative approaches that go beyond mere advertising.[18] Even purely private entertainment businesses have plugged anti-smoking messages.[19] Further, insurance companies invest significant resources in educating their customers about the dangers of smoking in addition to providing support for cessation.[20]

5.11 **U.S. Individuals are exposed to information regarding smoking in a vast range of media**

5.12 Individuals are also exposed to information regarding smoking in a plethora of sources. This was acknowledged by the Director of the National Cancer Institute, Dr. Joseph Heller, in 1957, who commented that "[n]ewspapers, radio, TV, and other media have done an excellent job covering [the dangers of smoking] and a very objective job. This is an exceedingly valuable way of informing the public."[21]

5.13 In their study of the awareness of the risks of smoking, Hammond et al., (2006)[22] also demonstrated that in the U.S. (and other jurisdictions), information on the dangers of smoking and anti-smoking content is disseminated via a diverse range of media, including on television, cigarette packs, magazine/newspaper, poster, radio, leaflets, shops/stores, movie theatre, and the internet. Significantly, the study found that smokers in the U.S. were almost twice as likely to indicate that they had been exposed to information about the dangers of smoking through television than through cigarette packs.[23] Individuals are now additionally exposed to information on the risks of smoking through social media, including on Facebook and Twitter.[24]

5.14 Exposure to smoking-related information from alternative sources has substantial advantages over FDA's proposed mandated pack warnings. First, discussions with health

---

14 https://www.aafp.org/patient-care/public-health/tobacco-nicotine/ask-act.html

15 https://www.cancer.org/healthy/stay-away-from-tobacco/guide-quitting-smoking.html

16 https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco/5-steps-to-quit-smoking

17 https://www.lung.org/stop-smoking/

18 See, for example, the development of a smart phone app by the Will Rogers Institute that helps smokers identify what triggers their desire to smoke and provides cessation strategies. https://wrinstitute.org/2017/ahoy-smokers/. Also, see the bilingual online tool provided by the MD Anderson Cancer Center https://www.mdanderson.org/about-md-anderson/community-services/aspire.html.

19 See, for example, https://www.newyorker.com/culture/culture-desk/mad-magazines-glorious-anti-smoking-campaign. A more recent example is https://www.prnewswire.com/news-releases/entertainment-industry-foundation-eif-and-warner-bros-partner-with-young-filmmakers-to-create-anti-smoking-psas-300257641.html.

20 See, for example, https://www.cigna.com/individuals-families/health-wellness/hw/medical-topics/quit-smoking-programs-aa153314, https://www.aetna.com/individuals-families/healthier-living-tips/how-to-quit-smoking.html, https://healthy.kaiserpermanente.org/health-wellness/healthy-lifestyle-programs/quit-smoking, and https://www.fepblue.org/wellness-resources-and-tools/incentive-programs/tobacco-cessation-incentive-program.

21 Testimony of J. Heller before the Subcommittee of the Committee on Government Operations, House of Representatives, "False and Misleading Advertising: Filter Tip Cigarettes," at 144 (July 18-19, 23-26, 1957).

22 D Hammond, G T Fong, A McNeill, R Borland, and K M Cummings (2006), “Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey,” Tobacco Control, 15(s3): iii19-iii25, Table 4.

23 D Hammond, G T Fong, A McNeill, R Borland, and K M Cummings (2006), “Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey,” Tobacco Control, 15(s3): iii19-iii25, Table 4.

24 https://www.cdc.gov/socialmedia/tools/guidelines/index.html

professionals are likely to be much more thorough and impactful than a static pack warning ever could be.[25] Similarly, media coverage of new smoking risk information will also be more current than a pack warning could possibly be, and media coverage by its very nature will induce more attention than pack warnings. Further, these anti-smoking information sources can be better targeted to specific groups.[26]

5.15 **The Universal Awareness of Smoking Risks is underscored by the Survey Data**

5.16 As demonstrated in the section below, federal and national polls have demonstrated that awareness of smoking-related risks have reached levels exceeding 80 percent (and often 90 percent) for years. This level of awareness represents a practical level of "saturation" with respect to people's reported awareness of smoking-related risks.

5.17 As a practical matter, getting to awareness levels above 80 or 90 percent is unrealistic, regardless of how ubiquitous and effective warnings and information campaigns are. This was underscored by the U.S. Surgeon General in his 1989 report, which acknowledged that it may be "unrealistic to set a goal above 90 percent of smokers for public knowledge." [27] It has been noted that some people will answer negatively no matter what question is asked (so called nay-saying or no-saying bias).[28]

General Perception of Cigarette Harm

5.18 The Population Assessment of Tobacco and Health (PATH) is a nationally representative longitudinal dataset of 45,971 adults and youth (12-17 years old) in the U.S. that was started explicitly to inform the FDA's regulatory decisions and actions with respect to smoking. The original baseline surveys (wave 1) were started in Fall 2013, and follow-up surveys were begun in Fall 2014 (wave 2), Fall 2015 (wave 3), and Fall 2016 (wave 4). As of August 2019, data for waves 1 through 3 are publicly available.[29]

5.19 The PATH study asks respondents "How harmful do you think cigarettes are to health?" providing the options: 1) Not at all harmful; 2) Slightly harmful; 3) Somewhat harmful; 4) Very harmful; and 5) Extremely harmful. Among adults, the average[30] response across waves 1 through 3 is 4.5 (mid-way between very harmful and extremely harmful). And it exhibits virtually no change throughout the waves.[31]

5.20 Given that the degree of difference between "Very" and "Extremely" is ambiguous, it is potentially helpful to examine what fraction of people believe cigarettes are either very or extremely harmful to your health. Using this measure, 91 percent of individuals across all

---

25 For a systematic review of studies on this point, see Malcolm Law and Jin Ling Tang (1995), "An Analysis of the Effectiveness of Interventions Intended to Help People Stop Smoking," Archives of Internal Medicine, 155(18): 1933-1941. A more recent review that likewise suggests that discussions with healthcare professionals, especially physicians, is associated with increased quit rates is Sherri Sheinfeld Gorin and Julia E. Heck, (2004), "Meta-Analysis of the Efficacy of Tobacco Counseling by Health Care Providers," Cancer Epidemiology, Biomarkers, and Prevention, 13(12): 2012-2022. A very recent review concluded the same thing, Jennifer M Wray, Jennifer S Funderburk, John D Acker, Laura O Wray, and Stephen A Maisto, (2018), "A Meta-Analysis of Brief Tobacco Interventions for Use in Integrated Primary Care," Nicotine and Tobacco Research, 20(12): 1418–1426. There is even evidence that interventions by dentists increase cessation; see Alan Carr and Jon Ebbert, (2012), "Interventions for tobacco cessation in the dental setting," Cochrane Systematic Review – Intervention.

26 See, for example, http://www.socialmarketing.com/campaign/my_greatest_enemy which targets the LGBT community. Also, https://www.nami.org/NAMI/media/NAMI-Media/downloads/Public-Policy-Platform_9-22-14.pdf which discusses anti-smoking strategies in the context of smokers with mental illness. College students are the focus of a joint program of the American Cancer Society and the CVS Foundation https://www.tobaccofreecampus.org/.

27 U.S. Public Health Service, "Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General," at 221 (1989).

28 For a brief discussion, see R. Michael Furr and Verne R. Bacharach, Psychometrics: An Introduction (2007) at 243.

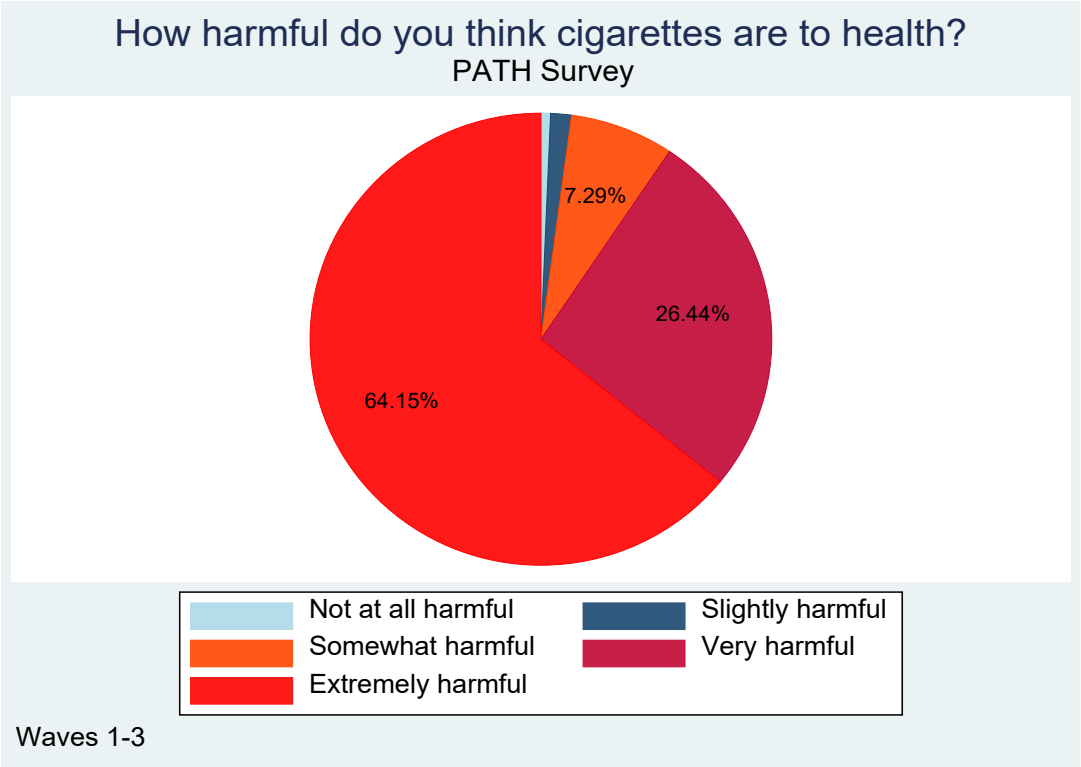
29 See https://www.accessdata.fda.gov/scripts/fdatrack/view/track_project.cfm?program=ctp&id=CTP-OS-Population-Assessment-of-Tobacco-and-Health-Study

30 Using the PATH longitudinal weights.

31 Wave 1 average: 4.55; Wave 2 average 4.51; and Wave 3 average 4.50.

three waves believe cigarette smoking is very or extremely harmful to health, and this measure does not vary appreciably over time.[32] Another 7 percent of individuals indicated cigarette smoking is "somewhat harmful," and 1.5 percent indicate it is "slightly harmful."

Figure 1: PATH Study - Response to "How harmful to do you think cigarettes are to health?"



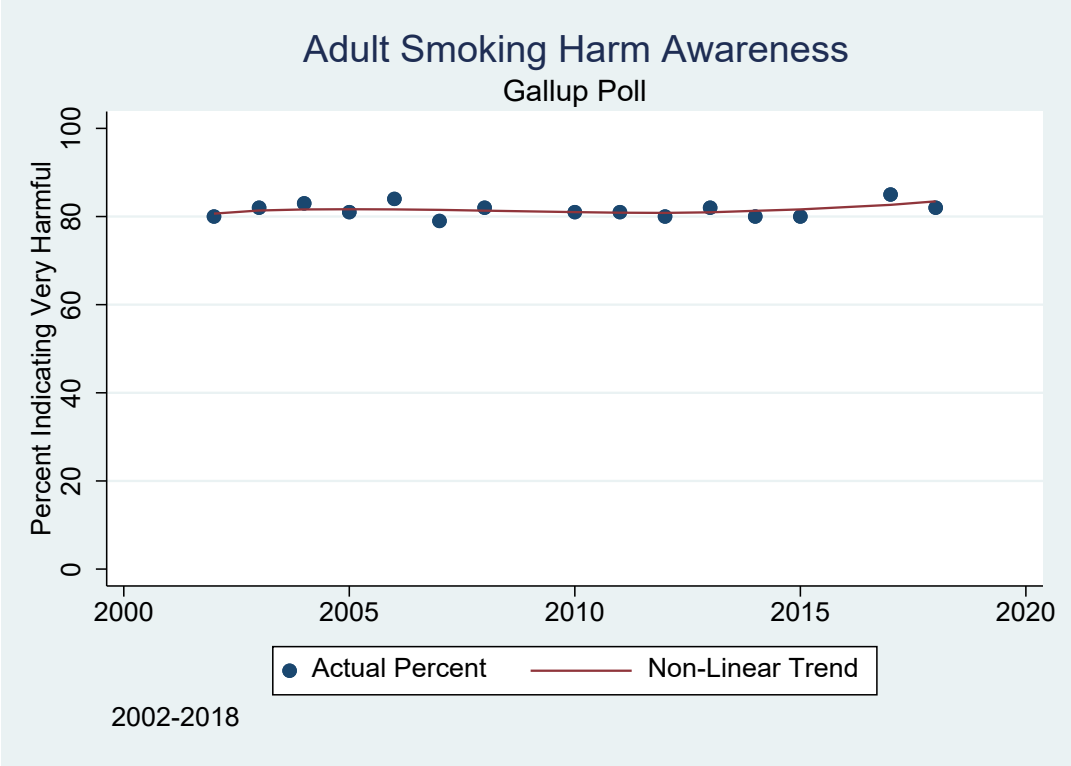
5.21 There is also very little substantive difference in the average response as between smokers and non-smokers (Smokers: 4.00; Non-Smokers: 4.65). Likewise, there is little difference across levels of education:

Table 3: PATH Study - Adult Cigarette Harm Awareness (by education)

Education Level	Mean
Less than high school	4.34
GED	4.32
High school graduate	4.43
Some college	4.53
Bachelor's degree	4.67
Advanced degree	4.72

[32] Wave 1: 91 percent; Wave 2: 90 percent; and Wave 3: 91 percent.

Figure 6: Gallup Poll – Adult Smoking Harm Awareness



5.26 Over the 2002 – 2018 time period, an average of 81.5 percent of respondents indicated that smoking is very harmful, and an additional 14 percent indicated it was somewhat harmful. There is no trend in the data – the fraction of people believing cigarette smoking to be very harmful to an individual's health has been consistently high for almost two decades. This actually understates the longevity and uniformity of this belief to some extent. Gallup earlier asked cigarette harm awareness questions in many previous years. These earlier questions also elicited high levels of awareness with respect to smoking harms.

Table 7: Gallup Poll – Adult Cigarette Harm Awareness (1946 – 1999)

Year	Question	Is Harmful	Not Harmful	Sample Size
1999	Do you think cigarettes smoking is harmful or not?	95%	4%	1,039
1990	Do you think that cigarette smoking is or is not harmful to your health?	96%	3%	1,240
1987	Is smoking harmful to your health?	94%	4%	2,059
1981	Do you think cigarette smoking is or is not harmful to your health?	91%	7%	1,535
1977	Do you think that cigarette smoking is or is not harmful to your health?	90%	7%	1,507
1954	Do you think cigarette smoking is harmful or not	70%	23%	1,500

Table 9

FDA Proposed Warnings	PATH Risk Awareness Question I am going to read you a list of diseases that may or may not be caused by smoking cigarettes. Based on what you know or believe, does smoking cause…
WARNING: Tobacco smoke can harm your children.	No question specific to children.
WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.	Lung disease in non-smokers from second-hand smoke [R01_AC9105]
WARNING: Smoking causes head and neck cancer.	No question specific to head and neck cancer.
WARNING: Smoking causes bladder cancer, which can lead to bloody urine.	Bladder cancer in smokers? [R01_AC9085]
WARNING: Smoking during pregnancy stunts fetal growth.	Harm to fetuses (or unborn children) during pregnancy from second-hand smoke? [R01_AC9115]
WARNING: Smoking can cause heart disease and strokes by clogging arteries.	Stroke in smokers? [R01_AC9060] Heart disease in smokers? [R01_AC9070]
WARNING: Smoking causes COPD, a lung disease that can be fatal.	Lung disease such as emphysema in smokers? [R01_AC9100]
WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.	No question specific to erectile dysfunction, but there is a question about reduced blood flow Poor circulation (also called peripheral vascular disease) in smokers? [R01_AC9080]
WARNING: Smoking reduces blood flow to the limbs, which can require amputation.	No question specific to amputations, but there is a question about reduced blood flow Poor circulation (also called peripheral vascular disease) in smokers? [R01_AC9080]
WARNING: Smoking causes type 2 diabetes, which raises blood sugar.	No question specific to diabetes
WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.	Blindness in smokers? [R01_AC9075]
WARNING: Smoking causes cataracts, which can lead to blindness.	Blindness in smokers? [R01_AC9075]

5.36 The results of this regression are shown in the table below.

Table 10

Effect of General Harm Assessment on Smoking Likelihood		
Fixed Effects Logistic Regression		
	Odds Ratio	Odds Ratio
How harmful do you think cigarettes are to health (1-5)	0.56 p < 0.01	
Indicated cigarettes are very or extremely harmful to health		0.38 p < 0.01
Agree that second-hand smoke can cause lung disease in non-smokers	1.00 Not statistically significant	0.99 Not statistically significant
Agree that smoking causes bladder cancer	1.11 Not statistically significant	1.10 Not statistically significant
Agree that smoking causes harm to unborn fetuses from second-hand smoke	0.96 Not statistically significant	0.98 Not statistically significant
Agree that smoking causes heart disease	0.87 Not statistically significant	0.86 Not statistically significant
Agree that smoking causes stroke	1.07 Not statistically significant	1.07 Not statistically significant
Agree that smoking causes lung disease	0.92 Not statistically significant	0.90 Not statistically significant
Agree that smoking causes poor circulation	0.82 Not statistically significant	0.79 Not statistically significant
Agree that smoking causes blindness	0.98 Not statistically significant	0.99 Not statistically significant
Individual Fixed Effects	Yes	Yes
Wave Fixed Effects	Yes	Yes
The outcome variable is a 0-1 indicator denoting whether the individual currently smokes cigarettes. Data from waves 1-3 are used in the estimation. The conditional logit model is used for estimation (“clogit” in Stata). Regressions are weighted according to the PATH		

Effect of General Harm Assessment on Smoking Likelihood
longitudinal weights averaged for each person over the three waves. Standard errors are clustered at the individual level.

5.37 While the overall harm assessment variable remains a statistically significant negative predictor of whether an individual smokes, none of the other risk awareness indicators for the particular risks that relate to the FDA's proposed warnings, is a statistically significant influence on whether a person is a smoker. Indeed, the findings of the model indicate that awareness of these additional subsidiary, or lesser publicized, risks have a zero direct effect on smoking behavior. In addition, if one examines the relationship between these particular risks and overall harm assessment, awareness of the particular risks that relate to the FDA's proposed warnings, generally have no statistically significant influence on a person's overall harm assessment of smoking.[46] Thus, the FDA's hypothesis that the proposed graphic warning will lead to a qualitatively "greater understanding" of smoking hazards by individuals is unsupported. Further, the FDA's speculation that such an "understanding" will lead to a decline in cigarette smoking is also unsupported. This calls into question the sensibility of focusing on individual risks that appear to have no effect on smoking behavior or generally on overall harm assessment. Instead of focusing on these specific risks it would seemingly be better to continue to tell people that smoking is extremely dangerous to one's health, focusing on the most severe and widespread risks such as death, and reserve outreach about specific lower level risks for campaigns which can be targeted to specific audiences insofar as they are actually deemed to be necessary by the FDA.

5.38 It is not possible to examine the effect of risk awareness related to a few of the FDA's proposed warnings – namely, smoking can harm your children, smoking causes head and neck cancer, and smoking causes diabetes – because these risks were not queried in the PATH survey. It is concerning that the FDA did not even use the survey that was explicitly initiated to inform its tobacco regulations to examine the risks it now proposes to use in its warnings.

5.39 While the foregoing analysis suggests that the FDA's warnings have no practical benefit in terms of actual smoking behavior, the agency suggests there are qualitative benefits from

[46] In order to carry out this inquiry, I performed a similar fixed effects logistic (conditional logit) regression where the outcome variable is whether someone believes smoking is very or extremely harmful to your health using awareness of the particular risks surveyed in the PATH data that best relate to the FDA's proposed warnings as the explanatory variables. Awareness of the risk of lung disease in non-smokers, awareness of the risk of bladder cancer, awareness of the harm to fetuses, awareness of the risk of heart disease, awareness of the risk of lung disease, and awareness of the risk of blindness all have no statistically significant impact on overall harm assessment. Only agreement that smoking may cause stroke in smokers and smoking may cause poor circulation (also called peripheral vascular disease) in smokers generate effects that imply statistically significant increases in overall harm assessment at the conventional 5 percent level. However, it is unlikely that introducing warnings about these risks (which are also not the exact same wording as the FDA's proposed warnings) would have much of an impact on increasing the overall harm assessment of the adult population for at least two reasons. First, both of these risks have quite high awareness already (across the three PATH waves, more than 80 percent of respondents agree that cigarette smoking may cause strokes in smokers and more than 82 percent agree that cigarette smoking may cause poor circulation in smokers). Second, it appears as though the contribution of these risks to overall harm assessment is very small. While it is not possible to estimate credible marginal effects from the conditional logit model (Stata's implementation of clogit requires the assumption that the individual fixed effect is zero in calculating the marginal effect; this would imply that people start off thinking that the overall harm of cigarettes is "none," a position that less than 1 percent of respondents hold), if one examines a linear probability model, the incremental effect of believing cigarette smoking may cause strokes in smokers and the incremental effect of believing cigarette smoking may cause poor circulation in smokers is to increase the likelihood that someone rates the overall harm of smoking as "very" or "extremely" harmful by only about 2 percent for each risk. In addition, it is at best unclear whether the warnings would actually increase public awareness of the corresponding risks, let alone that they would do so more effectively than less-intrusive alternatives such as text-only warnings, or smaller graphic warnings. *See, e.g.*, *infra at* ¶ 5.77 to 5.84 and ¶ 7.12.

merely informing individuals about specific risks beyond the general warnings of smoking's harm.

5.40 In the following section I provide data suggesting that awareness levels of most of these risks are already quite high, drawing into question whether there are even modest educational benefits to be had from the FDA's proposed warnings. I also cover awareness of the other major risks people are aware of with respect to smoking which likely are more important inputs to people's overall harm assessments.

Lung Cancer

5.41 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause lung cancer in smokers?" Across waves 1 through 3, 94 percent of respondents indicated that cigarette smoking does cause lung cancer. This fraction is comparable to the share of Australians surveyed in 2017 (a period where graphic health warnings had already been in place for a decade) who indicated smoking was very likely or likely to cause lung cancer (91 percent).[47] The number is similar when compared with a number of European countries in 2016 – Germany: 90 percent; Greece: 96 percent; Spain: 93 percent; Romania: 90 percent; Hungary: 83 percent; and Poland: 87 percent.[48] Although recent data are not available for awareness of the smoking and lung cancer risk in Canada and the United Kingdom, it is possible to compare older measures from sources other than the PATH survey. For example, in the 2002 International Tobacco Control Four Country Survey, the percent of survey respondents indicating that smoking causes lung cancer were – US: 94 percent; Canada: 95 percent; United Kingdom: 94 percent; and Australia: 94 percent.[49]

5.42 In the PATH data, awareness/agreement that cigarette smoking causes lung cancer does not meaningfully differ by race (White: 93 percent; Black: 92 percent; Other: 94 percent). It also does not vary by education level.

Table 11: PATH Study – Adult Awareness/Agreement that Cigarette Smoking Causes Lung Cancer

Education Level	Agree that Cigarette Smoking Causes Lung Cancer
Less than high school	90 Percent
GED	89 Percent
High school graduate	91 Percent
Some college	93 Percent
Bachelor's degree	96 Percent
Advanced degree	96 Percent

47 Emily Brennan, Kimberley Dunstone, Melanie Wakefield (2018), "Population awareness of tobacco-related harms: implications for refreshing graphic health warnings in Australia," Medical Journal of Australia, 209 (4): 173-174, 173.

48 Antigona C. Trofor, Sophia Papadakis, Lucia M. Lotrean, Cornel Radu-Loghin, Marius Eremia, Florin Mihaltan, Pete Driezen, Christina N. Kyriakos, Ute Mons, Tibor Demjén, Sarah O. Nogueira, Esteve Fernández, Yannis Tountas, Krzysztof Przewoźniak, Ann McNeill, Geoffrey T. Fong, Constantine I. Vardavas, on behalf of the EUREST-PLUS consortium (2018), "Knowledge of the health risks of smoking and impact of cigarette warning labels among tobacco users in six European countries: Findings from the EUREST-PLUS ITC Europe Surveys," Tobacco Induced Diseases, 16(2): A10.

49 See M Siahpush, A McNeill, D Hammond, and G T Fong (2006), "Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: results from the 2002 International Tobacco Control (ITC) Four Country Survey," Tobacco Control, 15(Suppl III): iii65–iii70, iii66 and D Hammond, G T Fong, A McNeill, R Borland, K M Cummings (2006), "Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey," Tobacco Control, 15(Suppl III):iii19–iii25, iii21.

Heart Disease

5.43 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause heart disease in smokers?" Across waves 1 to 3, 88 percent of adult PATH respondents indicated that cigarette smoking does cause heart disease in smokers. This compares to 86 percent in Australia in 2017.[50] The number also compares favorably with a number of European countries in 2016 – Germany: 82 percent; Greece: 95 percent; Spain: 82 percent; Romania: 88 percent; Hungary: 67 percent; and Poland: 83 percent.[51] Examining the older 2002 data suggests that U.S. (86 percent) awareness of the cigarette smoking and heart disease link has been comparable to that found in Canada (91 percent), Australia (89 percent), and the United Kingdom (90 percent).[52]

5.44 In the PATH data, awareness/agreement that cigarette smoking causes heart disease does not meaningfully differ by race (White: 88 percent; Black: 87 percent; Other: 86 percent). It also does not vary by education level.

Table 12: PATH Study – Adult Awareness/Agreement that Cigarette Smoking Causes Heart Disease

Education Level	Agree that Cigarette Smoking Causes Heart Disease
Less than high school	85 Percent
GED	85 Percent
High school graduate	86 Percent
Some college	89 Percent
Bachelor's degree	91 Percent
Advanced degree	90 Percent

Stroke

5.45 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause stroke in smokers?" Across waves 1 to 3, 80 percent of adult PATH respondents indicated that cigarette smoking does cause stroke in smokers. This compares to 83 percent in Australia in 2017.[53] The number also compares favorably with a number of European countries in 2016 – Germany: 72 percent; Greece: 69 percent; Spain: 56 percent; Romania: 78 percent; Hungary: 56 percent; and Poland: 61 percent.[54] Examining the older

50 Emily Brennan, Kimberley Dunstone, Melanie Wakefield (2018), "Population awareness of tobacco-related harms: implications for refreshing graphic health warnings in Australia," Medical Journal of Australia, 209 (4): 173-174, 173.

51 Antigona C. Trofor, Sophia Papadakis, Lucia M. Lotrean, Cornel Radu-Loghin, Marius Eremia, Florin Mihaltan, Pete Driezen, Christina N. Kyriakos, Ute Mons, Tibor Demjén, Sarah O. Nogueira, Esteve Fernández, Yannis Tountas, Krzysztof Przewoźniak, Ann McNeill, Geoffrey T. Fong, Constantine I. Vardavas, on behalf of the EUREST-PLUS consortium (2018), "Knowledge of the health risks of smoking and impact of cigarette warning labels among tobacco users in six European countries: Findings from the EUREST-PLUS ITC Europe Surveys," Tobacco Induced Diseases, 16(2): A10.

52 See M Siahpush, A McNeill, D Hammond, and G T Fong (2006), "Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: results from the 2002 International Tobacco Control (ITC) Four Country Survey," Tobacco Control, 15(Suppl III): iii65–7, iii66 and D Hammond, G T Fong, A McNeill, R Borland, K M Cummings (2006), "Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey," Tobacco Control, 15(Suppl III):iii19–iii25, iii21.

53 Emily Brennan, Kimberley Dunstone, Melanie Wakefield (2018), "Population awareness of tobacco-related harms: implications for refreshing graphic health warnings in Australia," Medical Journal of Australia, 209 (4): 173-174, 173.

54 Antigona C. Trofor, Sophia Papadakis, Lucia M. Lotrean, Cornel Radu-Loghin, Marius Eremia, Florin Mihaltan, Pete Driezen, Christina N. Kyriakos, Ute Mons, Tibor Demjén, Sarah O. Nogueira, Esteve Fernández, Yannis Tountas, Krzysztof Przewoźniak, Ann McNeill, Geoffrey T. Fong, Constantine I.

2002 data suggests that U.S. (73 percent) awareness of the cigarette smoking and stroke link has been comparable to that found in Canada (83 percent), Australia (81 percent), and the United Kingdom (70 percent). [55]

5.46 In the PATH data, awareness/agreement that cigarette smoking causes stroke does not meaningfully differ by race (White: 81 percent; Black: 77 percent; Other: 78 percent). It also does not vary by education level.

Table 13: PATH Study – Adult Awareness/Agreement that Cigarette Smoking Causes Stroke

Education Level	Agree that Cigarette Smoking Causes Stroke
Less than high school	77 Percent
GED	76 Percent
High school graduate	78 Percent
Some college	81 Percent
Bachelor's degree	83 Percent
Advanced degree	84 Percent

Poor Circulation

5.47 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause poor circulation in smokers?" Across waves 1 to 3, 82 percent of adult PATH respondents indicated that cigarette smoking does cause poor circulation in smokers. In the PATH data, awareness/agreement that cigarette smoking causes poor circulation does not meaningfully differ by race (White: 83 percent; Black: 80 percent; Other: 82 percent). It also does not vary by education level.

Table 14: PATH Study – Adult Awareness/Agreement that Cigarette Smoking Causes Poor Circulation

Education Level	Agree that Cigarette Smoking Causes Poor Circulation
Less than high school	78 Percent
GED	79 Percent
High school graduate	80 Percent
Some college	83 Percent
Bachelor's degree	86 Percent
Advanced degree	86 Percent

Lung Disease

5.48 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause lung disease such as emphysema in smokers?" Across waves 1 to 3, 94

[55] Vardavas, on behalf of the EUREST-PLUS consortium (2018), "Knowledge of the health risks of smoking and impact of cigarette warning labels among tobacco users in six European countries: Findings from the EUREST-PLUS ITC Europe Surveys," Tobacco Induced Diseases, 16(2): A10. See M Siahpush, A McNeill, D Hammond, and G T Fong (2006), "Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: results from the 2002 International Tobacco Control (ITC) Four Country Survey," Tobacco Control, 15(Suppl III): iii65–iii70, iii66 and D Hammond, G T Fong, A McNeill, R Borland, K M Cummings (2006), "Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey," Tobacco Control, 15(Suppl III):iii19–iii25, iii21.

percent of adult PATH respondents indicated that cigarette smoking does cause lung disease in smokers. This compares to 86 percent in Australia in 2017 (though the Australian survey appeared to restrict the question to emphysema alone).[56] The number also compares favorably with a number of European countries in 2016 – Germany: 69 percent; Greece: 79 percent; Spain: 75 percent; Romania: 66 percent; Hungary: 69 percent; and Poland: 77 percent.[57] The older 2002 data that allowed comparisons across the U.S., Canada, Australia, and the U.K. did not ask about lung disease.

5.49 In the PATH data, awareness/agreement that cigarette smoking causes lung disease does not meaningfully differ by race (White: 94 percent; Black: 91 percent; Other: 93 percent). It also does not vary by education level.

Table 15: PATH Study – Adult Awareness/Agreement that Cigarette Smoking Causes Lung Disease

Education Level	Agree that Cigarette Smoking Causes Lung Disease
Less than high school	90 Percent
GED	90 Percent
High school graduate	92 Percent
Some college	94 Percent
Bachelor's degree	97 Percent
Advanced degree	97 Percent

Other Cancers

Any Form of Cancer

5.50 The American Institute for Cancer Research has been asking a nationally representative sample about risk factors for cancer generically since 2001. Tobacco use regularly tops their list when it comes to respondent awareness, beating out genetic factors, diet and exercise issues, radon exposure, sunlight exposure, asbestos, and a host of other contributing factors, usually by a wide margin.[58]

Table 16: American Institute for Cancer Research Survey – Adult Awareness that tobacco use is a risk factor for Cancer

Year	Fraction Aware	Sample Size
2001	92%	750
2003	91%	1,025
2005	95%	1,010
2007	93%	1,022
2009	94%	1,021
2013	92%	1,026

56 Emily Brennan, Kimberley Dunstone, Melanie Wakefield (2018), "Population awareness of tobacco-related harms: implications for refreshing graphic health warnings in Australia," Medical Journal of Australia, 209 (4): 173-174, 173.

57 Antigona C. Trofor, Sophia Papadakis, Lucia M. Lotrean, Cornel Radu-Loghin, Marius Eremia, Florin Mihaltan, Pete Driezen, Christina N. Kyriakos, Ute Mons, Tibor Demjén, Sarah O. Nogueira, Esteve Fernández, Yannis Tountas, Krzysztof Przewoźniak, Ann McNeill, Geoffrey T. Fong, Constantine I. Vardavas, on behalf of the EUREST-PLUS consortium (2018), "Knowledge of the health risks of smoking and impact of cigarette warning labels among tobacco users in six European countries: Findings from the EUREST-PLUS ITC Europe Surveys," Tobacco Induced Diseases, 16(2): A10.

58 American Institute for Cancer Research, 2017 AICR Cancer Risk Awareness Survey Report, available at https://www.aicr.org/assets/docs/pdf/reports/AICR%20Cancer%20Awareness%20Report%202017_jan17%202017.pdf

Year	Fraction Aware	Sample Size
2015	94%	1,108
2017	93%	1,004

5.51 In 2017, there is no meaningful variation in the fraction of respondents aware that tobacco causes cancer based on race (White: 92 percent; Black: 91 percent; Hispanic: 94 percent) or based on education level (High School or Less: 89 percent; At Least Some College: 94 percent; More than College: 97 percent).

Bladder Cancer

5.52 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause bladder cancer in smokers?" Across waves 1 to 3, 58 percent of adult PATH respondents indicated that cigarette smoking does cause bladder cancer in smokers. This compares to 42 percent in Australia in 2017.[59] The other surveys did not ask about bladder cancer.

5.53 In the PATH data, awareness/agreement that cigarette smoking causes bladder cancer does not meaningfully differ by race (White: 58 percent; Black: 63 percent; Other: 59 percent). It also does not vary by education level.

Table 17: PATH Study – Adult Awareness/Agreement that Cigarette Smoking Causes Bladder Cancer

Education Level	Agree that Cigarette Smoking Causes Bladder Cancer
Less than high school	61 Percent
GED	55 Percent
High school graduate	58 Percent
Some college	58 Percent
Bachelor's degree	58 Percent
Advanced degree	58 Percent

5.54 While the bladder cancer awareness is lower than the awareness of the other risks covered here, recall that in the smoking regression presented above, awareness of the risk of bladder cancer was not associated with a higher likelihood that an individual would not smoke or an individual's overall harm assessment.[60] Indeed, awareness of this risk is likely to be of very low value to an individual.

Blindness

5.55 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause blindness in smokers?" Across waves 1 to 3, 46 percent of adult PATH respondents indicated that cigarette smoking does cause blindness in smokers. This compares favorably to the awareness figure from Australia (44 percent) In the PATH data, awareness/agreement that cigarette smoking causes blindness does not meaningfully differ by race (White: 44 percent; Black: 53 percent; Other: 47 percent). To the extent it varies by education, less educated people are more likely to believe smoking causes blindness.

59 Emily Brennan, Kimberley Dunstone, Melanie Wakefield (2018), "Population awareness of tobacco-related harms: implications for refreshing graphic health warnings in Australia," Medical Journal of Australia, 209 (4): 173-174, 173.

60 *See supra at* ¶ 5.36 to 5.38.

Table 18: PATH Study – Adult Awareness/Agreement that Cigarette Smoking Causes Blindness

Education Level	Agree that Cigarette Smoking Causes Blindness
Less than high school	53 Percent
GED	45 Percent
High school graduate	46 Percent
Some college	46 Percent
Bachelor's degree	43 Percent
Advanced degree	41 Percent

Harms from Second-Hand Smoke

5.56 Gallup has been asking a general question regarding the awareness of the harm that comes from second-hand smoke. Specifically, it has asked the question "In general, how harmful do you feel second-hand smoke is to adults – very harmful, somewhat harmful, not too harmful, or not at all harmful?"

Table 19: Gallup Poll – Adult Awareness of Harm from Second-Hand Smoke

Year	Very	Somewhat	Not Too	Not At All	Sample Size
2018	61%	27%	8%	3%	1,033
2017	59%	30%	5%	3%	1,021
2015	56%	31%	9%	3%	1,009
2013	59%	29%	7%	3%	2,027
2012	56%	32%	8%	4%	1,014
2011	54%	30%	9%	4%	1,016
2010	55%	31%	10%	4%	1,020
2008	56%	30%	9%	4%	1,016
2007	56%	29%	10%	5%	1,001
2006	56%	29%	8%	4%	1,007
2005	53%	31%	12%	3%	1,006
2004	55%	30%	9%	4%	2,250
2002	56%	31%	7%	4%	1,004
2001	52%	33%	9%	5%	1,038
1999	43%	39%	11%	5%	1,039
1997	55%	29%	9%	5%	1,013
1994	36%	42%	12%	6%	1,007

5.57 Throughout the 1994-2018 period, 85% of respondents, on average, indicated that second-hand smoke was either very or somewhat harmful to adults.

Harm to Fetuses During Pregnancy

5.58 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause harm to fetuses (or unborn children) during pregnancy from second-hand smoke?" Across waves 1 to 3, 86 percent of adult PATH respondents indicated that cigarette smoking does cause harm to fetuses. The surveys from other countries do not ask a comparable question.

Harm to Children

5.59 While none of the national surveys asking about second-hand smoke's effects specifically focused on the effects on children, it seems quite reasonable to assume that any beliefs about the harms of second-hand smoke would only be more pronounced when it comes to

children. On this point, there is an interesting study of 1,947 smoking parents[61] over the period 2009-2012 who were asked about the health effects of "third-hand" smoke on children.[62] In the sample, 91 percent of the subjects agreed that third-hand smoke is harmful to the health of infants and children.[63] It seems likely that if an over-whelming majority of smoking parents believe that even third-hand smoke harms the health of children, at least a comparable fraction would share the same belief about second-hand smoke.

Lung Disease in Non-Smokers

5.60 The PATH survey asks adult respondents "Based on what you know or believe, does smoking cause lung disease in non-smokers from second-hand smoke?" Across waves 1 to 3, 83 percent of adult PATH respondents indicated that cigarette smoking does cause lung disease in non-smokers from second-hand smoke. The surveys from other countries do not ask a comparable question.

5.61 In the PATH data, awareness/agreement that second-hand smoke causes lung disease in non-smokers does not meaningfully differ by race (White: 83 percent; Black: 83 percent; Other: 84 percent). It also does not vary by education level.

Table 20: PATH Study – Adult Awareness/Agreement that Second-Hand Smoke Causes Lung Disease in Non-Smokers

Education Level	Agree that Second-Hand Smoke Causes Lung Disease in Non-Smokers
Less than high school	82 Percent
GED	80 Percent
High school graduate	82 Percent
Some college	83 Percent
Bachelor's degree	86 Percent
Advanced degree	86 Percent

5.62 As shown above, there is high awareness for most of the topics covered in the FDA's proposed warnings.

Table 21: Awareness for Topics Covered in the FDA's Proposed Warnings

Proposed FDA Warning	Awareness Data Source	Awareness Level
WARNING: Tobacco smoke can harm your children	Third-hand smoke study	91 percent agreed third-hand smoke is harmful to children
WARNING: Tobacco smoke causes fatal lung disease in nonsmokers	PATH data	83 percent agreed that second-hand smoke causes lung disease in non-smokers
WARNING: Smoking causes head and neck cancer	American Institute for Cancer Research Survey	93 percent listed tobacco as a risk for cancer in 2017

61 The study participants were drawn from pediatric offices spread across Alaska, Connecticut, Illinois, Massachusetts, Maryland, Missouri, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Virginia, and West Virginia.

62 The study defines third-hand smoke as "Thirdhand smoke is a toxic residue that settles on indoor surfaces and remains long after tobacco smoking has taken place." Jeremy E. Drehmer, Deborah J. Ossip, Emara Nabi-Burza, Nancy A. Rigotti, Bethany Hipple, Heide Woo, Yuchiao Chang, and Jonathan P. Winickoff (2014), "Thirdhand Smoke Beliefs of Parents," Pediatrics, 133(4): p.2.

63 Jeremy E. Drehmer, Deborah J. Ossip, Emara Nabi-Burza, Nancy A. Rigotti, Bethany Hipple, Heide Woo, Yuchiao Chang, and Jonathan P. Winickoff (2014), "Thirdhand Smoke Beliefs of Parents," Pediatrics, 133(4): p.3.

no warnings changes occurred in the U.S., while warnings were made more prominent in the U.K.[67]

5.66 The indication that the U.S. has achieved extremely high levels of awareness without expanding warnings suggests that pack warnings like those proposed by the FDA are not necessary to inform individuals about the risks of smoking.

5.67 **The evidence demonstrates that the public overestimates the risks of smoking**

5.68 Given the omni-presence of smoking risk related information discussed above, there is a potential for individuals to over-estimate the risks of smoking.[68]

5.69 This possibility was first raised in a serious way by Kip Viscusi in a 1990 article. In that article, using a large nationally representative survey sample, Viscusi showed that a large majority of both smokers and non-smokers over-estimated the likelihood of developing lung cancer. Viscusi then combined those estimates with empirical models of smoking likelihood (in which beliefs about the likelihood of developing lung cancer reduce the probability someone will smoke), showing that people's over-estimates of their lung cancer risk led them to be less likely to smoke than they otherwise would have.[69]

5.70 If the goal of government policy is to induce people to not smoke, regardless of the person's own beliefs about the trade-offs between the individual costs and benefits of smoking, over-estimating risk would seem not to be a problem. However, in such a case, it would make more sense for government to regulate use directly. Instead, as indicated in 15 U.S. Code § 1331, the stated goal of government is for individuals to make fully informed smoking decisions. In that case, over-estimating cancer risk and its resulting effect on smoking is a problem.

5.71 This over-estimation result was duplicated in subsequent work by Viscusi, using a nationally representative survey of U.S. residents in 1997 and a Massachusetts-specific survey in 1998. Both surveys again suggested that smokers and non-smokers alike substantially over-estimated the lung cancer rate of smokers, as well as the contribution of smoking to over-all mortality and expected losses in lifespan. He again shows that this leads to a reduction in smoking (due to both never starting and due to quitting) relative to what would be expected if individuals were correctly informed.[70] Similar results have been estimated using data on the beliefs of adolescents.[71]

5.72 **Given the high level of consumer awareness, the FDA's proposed warnings cannot be expected to be effective**

5.73 U.S. data are clear that individuals are well informed about the general health risk of smoking. They are also well informed about many individual risks that are associated with smoking and have been for quite some time.

---

67 Louise M. Hassan, Edward Shiu, James F. Thrasher, Geoffrey T. Fong, and Gerard Hastings, (2008), "Exploring the effectiveness of cigarette warning labels: findings from the United States and United Kingdom arms of the International Tobacco Control (ITC) Four Country Survey," International Journal of Nonprofit and Voluntary Sector Marketing, 13: 263–274, at Table 3.

68 The evidence discussed below takes as given the conventional estimates of smoking risks from the public health literature. That said, it is interesting to note that Michael Darden (2017), "Smoking, Expectations, and Health: A Dynamic Stochastic Model of Lifetime Smoking Behavior," Journal of Political Economy, 125(5): 1465-1522 finds that the conventional estimates are overstated due to their failure to adequately account for selection effects. That is, people who choose to smoke generally have lower lifespans and worse health independently of their smoking. He finds that once selection is accounted for, previous estimates of the causal effect of smoking on lifespan might be overstated by a factor of two. If this is correct, all of the research discussed below actually understates the extent to which people over-estimate the effect of smoking on health.

69 W. Kip Viscusi (1990), "Do Smokers Underestimate Risks?" Journal of Political Economy, 98(6): 1253-1269.

70 Kip Viscusi and Jahn K. Hakes (2008), "Risk Beliefs and Smoking Behavior," Economic Inquiry, 46(1): 45-59.

71 See, for example, Daniel Romer and Patrick Jamieson(2001), "Do adolescents appreciate the risks of smoking? Evidence from a national survey," Journal of Adolescent Health, 29(1):12–21.

5.74 None of the FDA's proposed new warnings conveys meaningful new information of which the public (adults and youth) is unaware. For this reason, the proposed FDA warnings cannot be expected to have any incrementally positive impact on either overall risk awareness or behavior.

5.75 This is supported by a study by Byrne et al., (2014)[72] which considered alternatives to the FDA proposed cigarette warning labels. The authors found that "[f]indings from all three study samples suggest that cigarette warning labels may not succeed in increasing health risk beliefs because they are already quite high" and that "[t]here are no significant differences in the level of health risk beliefs generated by the full-color graphic warning labels compared to alternatives [black and white graphic, text only, SGR warning, no warning]. This may be due to a ceiling effect, wherein health risk beliefs are already very high and exposure to package warning labels may not have room to further influence those beliefs."

5.76 **FDA's Existing Warnings for other Products Underscores that there is no need for Graphic Warnings**

5.77 The FDA has a long history with warnings and labeling requirements.[73] Both for hazardous substances and risky pharmaceuticals, *inter alia*, the FDA regulates what must be included in the labeling of thousands of consumer products and pharmaceuticals.[74] The guiding principle for the warnings included with these products is that relevant, factual information is provided to the consumer, with the assumption that this information is sufficient for the purchaser to make informed decisions with respect to consuming the products.[75] These warnings are rarely, if ever, graphical, and their size is kept modest, relegated to a single location on the product packaging.[76] Once the information is provided, there is no gain to providing it in a larger font, or in more intrusive locations. Once information is known, amplifying it provides little in terms of marginal value.[77] It is not at all clear why cigarette packaging should be any different. If anything, given the previous discussion about risk awareness, consumers are arguably already better informed about the risks of cigarettes than they are about the medicines they take.

5.78 **Efficacy of Fear and Disgust-Based Warnings**

5.79 Beyond mere information, some advocates have suggested using graphic warnings, such as those proposed by FDA, to elicit emotional responses from cigarette consumers, such as fear or disgust, on the assumption that doing so will lead fewer people to smoke/more smokers to quit smoking.

5.80 Whilst the FDA purports to not rely upon fear and disgust-based warnings, and claims that the proposed warnings are "photorealistic images…presented in a realistic and objective format"[78], in reality it is evident that the FDA is appealing to fear and disgust. For this reason,

---

72 Byrne S, Katz SJ, Mathios A, Niederdeppe J. Do the ends justify the means? A test of alternatives to the FDA proposed cigarette warning labels. Health Commun. 2015;30(7):680-93. doi: 10.1080/10410236.2014.895282.

73 U.S. Food & Drug Admin., Milestones in U.S. Food and Drug Law History, available at https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history

74 U.S. Food & Drug Admin., Milestones in U.S. Food and Drug Law History, available at https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history

75 Frederick H. Degnan, The Food Label and the Right-to-Know, 52 FOOD & DRUG L.J. 49 (1997), at 54.

76 See for example: 21 CFR § 201.66(d)(2) (Over-the-counter drugs); 21 CFR § 201.66(c)(5)(viii), (ix), (x) (Over-the-counter drugs); FDA, OTC Labeling Questions and Answers, available at www.fda.gov/about-fda/center-drug-evaluation-and-research/otc-labeling-questions-and-answers (Over-the-counter drugs); 21 CFR § 201.57(d) (Prescription Drugs); 21 CFR § 201.57(a)(9), 21 CFR § 201.57(a)(10) (Prescription Drugs); 21 CFR § 740.2 (Cosmetics); and 21 CFR § 101.93(e) (Nutritional supplements).

77 Lars Noah, The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” about Consumer Product Hazards, YALE J. REG., Vol. 11, 293 (1994), at 381.

78 Federal Register/ Vol. 84, No. 159/ Friday, August 16, 2019/ Proposed Rules, p. 42770.

the warnings are likely to incur all of the adverse effects of fear and disgust-based warnings discussed below. I note that the FDA did not test, report testing, and/ or provide any qualitative research disclosing that it had tried to prevent emotional responses to the proposed warnings or that it tried to try to mitigate any such effect.

5.81 The empirical evidence on the use of emotional appeals in warnings is mixed at best, and substantial literature suggests that fear-based warnings are not generally effective in changing actual behavior. For example:

5.81.1 Kessels and co-authors found that smokers were less attentive to commercials promoting the health benefits of quitting smoking that were threatening, as opposed to merely factual commercials. They concluded that "[o]ur findings support recent findings in the fear appeal literature which suggest that people react defensively to threatening health information. In addition to the findings of earlier studies that used pictures (*citations omitted*), this study found neuroscientific evidence that threatening health commercials cause more attentional avoidance among those for whom the health threat is self-relevant."[79]

5.81.2 A study by Ruiter and colleagues, which reviewed the current state of the empirical evidence on the efficacy of fear appeals, concluded that "[b]y focusing primarily on threat severity, the evidence on fear appeals is not translated into the design of health messages. Current evidence shows that information about the severity of possible negative consequences from risk behaviour may prompt defensive responses."[80]

5.81.3 Kok and colleagues reviewed the extant empirical evidence on fear appeals. They found that "[p]eople falsely believe that fear appeals promote health behaviours. Some of our colleagues in the field do too; thereby as has been shown above, ignoring theory and misinterpreting evidence. Carefully examining available theory and evidence led us to the conclusion that fear appeals are only effective in case of high self-efficacy; a situation that is quite rare in health promotion practice. Thus fear appeals may be useful when they are combined, in a non-threatening way, with messages that improve self-efficacy and help people change their behaviour…The belief in fear appeals, in particular scary pictures, is false. Again, this evidence is not about smoking; this evidence is on all kinds of health promoting behaviour."[81]

5.81.4 Kohn and co-authors evaluated the relative effectiveness of three filmed emotional appeals against drinking and driving and among high-school students. They found that while high-threat emotional appeals evoked the highest emotional response amongst participants, none of the films had discernible effects on self-reported

---

79 Loes T. E. Kessels, Robert A. C. Ruiter, Liesbeth Wouters, and Bernadette M. Jansma (2014), "Neuroscientific evidence for defensive avoidance of fear appeals," International Journal of Psychology, 49(2): 80-88, 86. This is consistent with some of the authors' previous work which also showed that threatening messages induced disengagement among smokers; see Loes T. E. Kessels, Robert A. C. Ruiter, and Bernadette M. Jansma.(2010), "Increased attention but more efficient disengagement: Neuroscientific evidence for defensive processing of threatening health information." Health Psychology, 29(4): 346–354 even though the threatening messages did appear to be associated with greater attention. Subsequent work suggested that inducing smokers to engage in self-affirmation techniques could reduce avoidance of threatening messages among smokers, but the affirmation exercise was more complicated than could be effectuated through a product warning. Namely, the exercise had "Participants in the self-affirmation condition identified their most important value and wrote about why this value is important to them and how they used this value in daily life. Participants in the nonaffirmed condition identified their least important value and explained why this value might be important to another student." See Loes Kessels, Peter Harris, Robert Ruiter, and William Klein (2016), "Attentional effects of self-affirmation in response to graphic antismoking images," Health Psychology, 35(8), 891-897, 893.

80 Ruiter et al (2014) Sixty years of fear appeal research: Current state of the evidence. Int J Psychol. 2014 Apr;49(2):63-70. doi: 10.1002/ijop.12042.

81 Kok et al (2018), Ignoring theory and misinterpreting evidence: the false belief in fear appeals. Health Psychology Review, 12:2, 111-125, DOI: 10.1080/17437199.2017.1415767.

for the health effects where the researchers did find a uniformly higher awareness in Canada, impotence and lung cancer associated with second-hand smoke, the Canadian awareness rates were much lower than the U.S. for the other health risks. This suggests that graphic health warnings are no silver bullet and argues in favor of using the kinds of risk communication approaches that led to near universal awareness of, for example, smoking's link to lung cancer, such as text warnings and public health awareness campaigns.

7.11 **Is There Evidence That Bigger (and More) Is Better?**

7.12 Built into the FDA's proposal is the idea that pack warnings should be large and should take up multiple sections of the pack in order to communicate risk information effectively. This assumption is belied by the literature the FDA cites. For example, Skurka et al randomized youth and adult smokers across pack images that either had no graphic health warnings, graphic warnings that covered 30 percent of the pack image or 50 percent of the pack image. The researchers found no consistent evidence of a beneficial impact of 50 percent graphic health warnings. For example, the researchers found no differences between the control (no graphic) image and 30 percent warnings or between the control (no graphic) image and 50 percent warnings in terms of risk beliefs for adults.[123] They also found no statistically significant difference in quit intentions between 30 percent and 50 percent warnings for adults or between the control (no graphic condition) and either warning size and smoking susceptibility among young people.[124] The lack of an effect on risk beliefs is likewise found in Brewer et al where smokers were randomized between packs with text warnings and packs with graphic warnings on both the front and back of the pack.[125] Klein et al also find that graphic warning size does not affect risk awareness/recall (in fact, in their study, subjects on average did worse in terms of recall in the condition where the graphic covered a third of the pack as opposed to the condition where only 20 percent was covered, though the differences were not generally statistically significant).[126] To the extent that the size/area of a pack covered is examined in the literature cited by the FDA, the studies reject the notion that warnings that are bigger or cover more of the area on a pack more effectively convey information to smokers. This draws into question any regulatory proposal that calls for large graphic health warnings or warnings that take up more of the package because they are printed in multiple locations on the pack.

8. CRITIQUE OF FDA'S IMPACT ANALYSIS AND FDA STUDIES

8.1 Much like the flawed graphic health warnings literature in general, the FDA's own studies are problematic. First and foremost, these studies do not explore any outcomes related to actual smoking behavior. Instead, these studies merely examine the effects of the proposed warnings on self-reported measures of whether the graphic warnings provided new information, whether participants learned something from the warning, whether the warnings led participants to think about the risks contained in the warnings, whether participants found

---

Tobacco Control (ITC) Four Country Survey," Tobacco Control, 15(s3): iii19-iii25, Table 5 shows that there is no significant difference for heart disease (between Canada and UK/Australia), stroke (between Canada and Australia), and lung cancer among smokers (between Canada and US/UK/Australia).

123 Chris Skurka, Deena Kemp, Julie Davydova, James Thrasher, Sahara Byrne, Amelia Greiner Safi, Rosemary Avery, Michael Dorf, Alan Mathios, Leah Scolere, and Jeff Niederdeppe (2017), "Effects of 30% and 50% Cigarette Pack Graphic Warning Labels on Visual Attention, Negative Affect, Quit Intentions, and Smoking Susceptibility among Disadvantaged Populations in the United States," Nicotine and Tobacco Research, 20(7): 859-866, 862-863.

124 Chris Skurka, Deena Kemp, Julie Davydova, James Thrasher, Sahara Byrne, Amelia Greiner Safi, Rosemary Avery, Michael Dorf, Alan Mthios, Leah Scolere, and Jeff Niederdeppe (2017), "Effects of 30% and 50% Cigarette Pack Graphic Warning Labels on Visual Attention, Negative Affect, Quit Intentions, and Smoking Susceptibility among Disadvantaged Populations in the United States," Nicotine and Tobacco Research, 20(7): 859-866, 864-865.

125 Noel Brewer, Humberto Parada, Marissa Hall, Marcella Boynton, Seth Noar and Kurt Ribisl (2019), "Understanding Why Pictorial Cigarette Pack Warnings Increase Quit Attempts," Annals of Behavioral Medicine, 53: 232-243, Table 2.

126 Elizabeth Klein, Abigail Shoben, Sarah Krygowski, Amy Ferketich, Micah Berman, Ellen Peters, Unnava Rao, and Mary Ellen Wewers (2015), "Does Size Impact Attention and Recall of Graphic Health Warnings," Tobacco Regulatory Science, 1(2): 175-185, Table 4.

the warnings to be informative, understandable, believable, and factual, whether the warnings affected beliefs about the link between smoking and each of the health consequences presented in the warnings, whether the warning was perceived to help participants understand the negative health effects of smoking, and how the graphic health warnings affected recall of the warning content at a two week follow-up. The FDA provides no foundation for determining whether these measures reflect what is necessary to make adequately informed decisions with respect to smoking. The FDA merely assumes that it is necessary that people are aware of the risks covered in the graphic health warnings in order to make adequately informed decisions. However, the FDA does not address why awareness of these specific risks is necessary given that more than 90 percent of their study subjects already believe that smoking can kill you.[127] Presumably, knowing that smoking is deadly is enough information to discourage them from smoking, whereas for those who know smoking is deadly but are still inclined to smoke, risks like blindness and erectile dysfunction are likely not material. Likewise, the FDA provides no evidence nor claims that any of these outcomes actually affect ultimate smoking behaviors. Accordingly, it cannot credibly assert that the information conveyed by the proposed warnings is valuable.

8.2 But even ignoring these major limitations of the FDA studies, many of the proposed warnings do not fare particularly well measured by the FDA's own metrics. For example, for the FDA's bladder cancer graphic health warning, while it does seem to be viewed by people as providing new information, it did not significantly affect how much they thought about the risk or their health beliefs about the risks, not did it significantly affect the degree to which people found the warning to be informative. The bladder cancer graphic health warning actually reduced people's ratings of the believability and factuality of the risk.[128] Similar inconsistencies can be found for the erectile dysfunction graphic health warning, which people rated as providing new knowledge, but actually reduced the likelihood they would think about the risk. Likewise with the diabetes graphic health warning, which provided new information but reduced believability and assessment of the factuality of the claim by those who viewed the graphic warning and similar inconsistencies are found with respect to the graphic health warnings dealing with blindness.[129] In the 2nd FDA study, many of the tested warnings actually were associated with reduced perception of the factuality of the risk, including both blindness warnings, the diabetes warning, and the erectile dysfunction warning.[130] Although I focus on these warnings given that they are the only ones where the analysis above suggests that general awareness may not already be quite high, there are similarly large discrepancies across the metrics used to evaluate the efficacy of the other proposed graphic warnings.

8.3 It is already questionable to begin with to judge the worth of graphic health warnings without tying them to actual smoking behavior, but it is especially problematic motivating the graphic warnings on a purely information-providing basis when they do not appear to consistently provide believable information, or when they are actually viewed as less factual than non-graphic warnings. This leaves open the strong possibility that the warnings provide very little, if any, value. To the extent they undermine believability or belief in the underlying facts covered by the warnings, they may actually provide negative benefits even before the production and administration costs are considered.

8.4 Beyond these critical problems, even taken on their own terms, the FDA studies have significant short-comings which makes them unreliable. For example, its first quantitative

---

127 See, for example, Experimental Study of Cigarette Warnings: Study 2 Report OMB Control No. 0910-0866 May 2019, Table 3-6, page 3-13 (showing 30% "agree", and 61% "strongly agree" that smoking can kill you).

128 See Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report OMB Control No. 0910-0848 April 2018, Table 4-1 (page 83/143 in pdf). The bladder cancer warning also fare poorly in terms of factuality in Experimental Study of Cigarette Warnings: Study 2 Report OMB Control No. 0910-0866 May 2019, Table 3-3, page 3-5.

129 See Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report OMB Control No. 0910-0848 April 2018, Table 4-1 (page 84/143 in pdf).

130 Experimental Study of Cigarette Warnings: Study 2 Report OMB Control No. 0910-0866 May 2019, Table 3-3, page 3-5.

study did not consider a representative sample of the U.S. population. The Office of Management and Budget granted only a limited approval of that study and noted that, "[d]ue to the study design, convenience sampling methodology, and methods of analyses—significant limitations exist with regard to the generalizability of results from this study . . . Because of these limitations, the relationship between treatment and outcomes [that FDA] find[s] in [its] study may not generalize to the broader U.S. population.[131]" Because of this, the FDA now acknowledges that the survey for this study "used a convenience sample rather than a probability sample, and the results are not nationally representative.[132]" The second study likewise did not use a nationally representative sample.[133] Moreover, neither study had been subjected to peer review prior to the FDA announcing its proposed rule.[134]

8.5 The FDA's preliminary regulatory impact analysis offered in support of its rule is woefully incomplete and unreliable. At a minimum, a thorough and reliable impact assessment must measure and value the costs and the benefits of the proposed regulation. The FDA's impact assessment does not even meet this low bar. On the benefit side, the FDA notes "The purpose of the rule is to promote greater public understanding of the negative health consequences of smoking." The agency does not, however, actually value this claimed increase to public understanding, stating "The direct economic benefits of providing information on cigarette health warnings are difficult to quantify, and we do not predict the size of these benefits at this time." Given the foregoing analysis suggesting that graphic health warnings do not have any effect on actual smoking behavior, it is difficult to understand what this value would be. While there is a large empirical literature on the value of information, in most cases these valuations are estimated through the effect of the information on behavior.[135] Another approach would be to come up with willingness to pay estimates for this information. Willingness to pay estimates, however, are likely to be quite low given that the risk information is freely and easily available on government websites[136] as well as from a host of other sources.[137]

8.6 The FDA instead provides a break even analysis wherein they simply divide the expected costs of the regulation by the number of cigarette packs sold in the US, yielding a conclusion that if the information benefits accrue to one cent per pack sold, the regulation will generate a net benefit to society. The agency provides no way for the public to judge whether this one cent figure is likely to be met. Given that the agency does not quantify what it expects the information effect of its warnings to be, much less value them monetarily, the agency has not actually provided any basis to suggest that this regulation will in fact improve public welfare. As suggested above, it is not beyond reason to think the per pack benefits could actually be negative even without bringing the costs of the regulation into the analysis.

---

131 OMB, Notice of Office of Management and Budget Action, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings, Ref. No. 201708-0910-011 (Jan. 29, 2018), https://tinyurl.com/ybwk7ptv.

132 Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report OMB Control No. 0910-0848 April 2018, 4-4.

133 Experimental Study of Cigarette Warnings: Study 2 Report OMB Control No. 0910-0866 May 2019, 4-2 ("[T]he survey used a convenience sample rather than a probability sample, and the results are not nationally representative.").

134 84 Fed. Reg. 42,768 n.6 (first quantitative study); id. 42,772 n.9 (second quantitative study). Both studies therefore state that they have been "distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines," and that they have "not been formally disseminated by FDA," and that they do "not represent and should not be construed to represent any agency determination or policy."

135 See, for example, Ginger Zhe Jin and Alan T. Sorensen (2006), "Information And Consumer Choice: The Value Of Publicized Health Plan Ratings," Journal of Health Economics, 25(2), 248-275 or Michael Chernew, Gautam Gowrisankaran, and Dennis P. Scanlon (2008), "Learning and the Value of Information: Evidence from Health Plan Report Cards," Journal of Econometrics 144(1): 156-74.

136 See, for example, https://www.cdc.gov/tobacco/basic_information/health_effects/index.htm or https://smokefree.gov

137 See, for example, https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/health-risks-of-smoking-tobacco.html

Exhibit D

Report of
Prof. Jan-Benedict Steenkamp

C. Knox Massey Distinguished Professor of Marketing
Kenan-Flagler Business School
University of North Carolina at Chapel Hill

September 27, 2019

3. THE FDA HAS FOUND THAT ANTI-SMOKING, EDUCATION-BASED SOCIAL MARKETING CAMPAIGNS ARE EFFECTIVE

3.1. Introduction

Social marketing campaigns refer to public service messages transmitted over a range of communication platforms to reach a target segment. In the context of tobacco control, a key goal of anti-smoking social marketing campaigns is to provide information about the negative consequences of tobacco. The FDA has found that social marketing campaigns can be particularly effective because they are dynamic tools that can, *inter alia*, target specific segments of the market and tailor content so that messaging is more effective.[4] In contrast, basic marketing teaches that a one-size-fits-all message, such as would be the case with the FDA's proposed graphic health warnings, is simply less effective from an informational perspective than messages targeted at specific demographic and lifestyle segments (e.g., youth or LGBTQ).

In this chapter, I provide a review of important recent U.S.-based anti-smoking social marketing campaigns that have been implemented by the FDA and other entities. I base my review on publicly available FDA/other entity evaluation reports that were commissioned to assess the success (or lack thereof) of anti-smoking social marketing campaigns. I report on the following six major anti-tobacco social marketing campaigns that are still running:

- Truth Initiative's *truth*® campaign (2000–present)
- Centers for Disease Control and Prevention ("CDC") *Tips From Former Smokers* (2012–present)
- FDA's *The Real Cost* campaign (2014–present)
- FDA's *Fresh Empire* campaign (2015–present)
- FDA's *This Free Life* campaign (2016–present)
- FDA's *Every Try Counts* campaign (2017–present)

After discussing these current campaigns (section 3.2), I review and synthesize the literature on two important issues: (1) the effectiveness of anti-smoking campaigns in targeting the youth segment (< 18 years), which is of particular concern to public-health officials (section 3.3); and (2) the assessment of the economic outcomes of anti-smoking social marketing campaigns—an important consideration when the campaign is paid for by the tax payer (section 3.4). I provide my conclusions in section 3.5.

[4] Other agencies have likewise concluded that social marketing campaigns are an effective way to educate the public. For example, the National Highway Traffic Safety Administration (NHTSA) has run a "Click It or Ticket" campaign designed to increase the number of people who wear seat belts, and the Office of National Drug Control Policy has run a National Youth Anti-Drug Media Campaign designed to reduce drug use. This report does not attempt to summarize all such campaigns.

3.2. Review of important recent U.S.-based anti-smoking social marketing campaigns

A. Truth Initiative's *truth* Campaign (2000–present)

Background and description of the campaign

The *truth*® campaign is the oldest national tobacco counter-marketing campaign targeting youth smoking prevention and education. It is conducted by Truth Initiative (formerly known as American Legacy Foundation), a nonprofit public health organization.[5] The primary target segment for *truth*® is adolescents aged 12–17 years who are likely to experiment with smoking.

In 2014, Truth Initiative relaunched *truth*® with the "FinishIt" campaign, focused on a slightly older target audience of youth and young adults, aged 15–21. The new campaign theme is: "be the generation that ends smoking," with research among the target youth segment revealing that "today's teens are less interested in protesting against the tobacco industry, and more interested in driving positive collective action, being the generation that ends smoking for good."[6] Campaign advertisements and alternative truth-related content are delivered on television channels and in TV shows popular among the target audience, including MTV and Comedy Central, and online through banner ads, online video ads, homepage takeovers, paid promotions on social media sites, branded social media sites (#FinishIt), and a branded campaign website. The campaign is delivered to 210 U.S. media markets through TV commercials, websites, radio ads, and social media.[7]

The new FinishIt campaign is innovative in another aspect. It explicitly adopts a branding strategy, promoting *truth*® as a brand in its own right. Only recently have campaigns that promote health-related behaviors adopted branding, a well-established marketing strategy proven to enhance communication efforts. Health promotion campaigns apply traditional branding principles to promote some type of health behavior as a "product" in exchange for consumer health and wellbeing. The desired behavior is not a purchase decision, rather it is a voluntary, health-promoting behavior that the consumer is asked to initiate or maintain. The associations that consumers make with public health brands can help expedite the communication of branded health messages and engagement in healthy behaviors or lifestyles. For health behavior campaigns, branding can establish long-term value, enabling brand affinity to build with the target audience so that they ultimately adopt and sustain healthy behaviors.[8]

Results

The Truth Campaign has effectively used social marketing to communicate with the intended recipients.[9] For example, one study by Farrelly et al. (2002) found that 10 months into the campaign, awareness of specific campaign advertisements among 12- to 17-year-olds was 75%

---

[5] Funding for the American Legacy Foundation and the *truth*® campaign came from the 1998 Master Settlement Agreement between the tobacco industry, 46 states, and five U.S. territories.

[6] Lee, N.R. and P. Kotler (2020), *Social Marketing: Behavior Change for the Social Good*, Los Angeles, CA: Sage, 6th edition, p. 400.

[7] Vallone, D. et al. (2017), "The Effect of Branding to Promote Healthy Behavior: Reducing Tobacco Use among Youth and Young Adults," *International Journal of Environmental Research and Public Health*, 14, 1517; doi:10.3390/ijerph14121517.

[8] This paragraph is taken from Vallone et al. (2017), op. cit., pp. 1–2.

[9] https://truthinitiative.org/who-we-are/our-mission

for "truth."[10] They also reported that exposure to the campaign was associated with significant increase in the odds of *agreeing* with empowerment and action statements "I want to be involved in efforts to get rid of smoking" (35% increase in the odds to agree with this statement), "Taking a stand against smoking is important to me" (+163%), "Not smoking is a way to express independence" (+46%) and with a significant increase in disagreeing with "Smoking makes people your age look cool or fit in" (+52%). The authors conclude: "*In summary, our findings suggest that an aggressive national tobacco countermarketing campaign can have a dramatic influence within a short period of time on attitudes toward tobacco and the tobacco industry*."[11]

Another study by Farrally et al. (2009) analyzed data obtained from a nationally representative cohort of 8,904 adolescents 12–17 years for the period 2000–2004.[12] They found that "*The current study strengthens the available evidence for antismoking campaigns as a viable strategy for preventing youth smoking.*"[13]

Before the relaunch in 2014, *truth*'s primary target segment was adolescents, aged 12–17 years. However, Richardson et al. (2010) were interested whether the campaign had beneficial spillover effects for a secondary target segment, viz. young adults aged 18–24 years old. [14] These authors found that a majority of young adults were aware of the *truth* campaign, and that campaign awareness was associated with multiple anti-smoking attitudes.

Vallone et al. (2018) provided evidence on the impact of the new *truth* campaign, FinishIt, launched in 2014. These authors report that *truth* ad awareness is significantly associated with increases in targeted anti-tobacco attitudes.[15]

The effectiveness of *truth*®'s innovative approach to market the campaign as a brand to promote health behaviors was examined in Vallone et al. (2017).[16] They measure the "equity" of *truth*.[17] The authors found that: "*Branding can help make healthy behaviors more personally compelling and culturally relevant for a target audience. Comprehensive studies of audience preferences and culture helps to create compelling brands that reflect the passion points of the intended audience, and which are tied to timely and culturally relevant trends. In the last decade, tobacco use patterns have changed, the communications landscape has significantly shifted, and a new generation of youths and young adults espouse different attitudes, beliefs and behaviors. Branding strategies,*

---

[10] Farrally, M.C. et al. (2002), "Getting to the Truth: Evaluating National Tobacco Countermarketing Campaigns," *American Journal of Public Health*, 92, pp. 901–907.
[11] Farrally et al. (2002), op. cit., p. 906.
[12] Farrally et al. (2002), op. cit.
[13] Farrally, M.C. et al. (2009), "The Influence of the National truth® Campaign on Smoking Initiation," *American Journal of Preventive Medicine*, 36 (5), pp. 379-384; Quote taken from p. 379.
[14] Richardson, A.K. et al. (2010), "Evidence for truth®: The Young Adult Response to a Youth-Focused Anti-Smoking Media Campaign," *American Journal of Preventive Medicine*, 39 (6), pp. 500-506.
[15] Vallone, D. et al., (2018), "Evidence of the Impact of the truth FinishIt Campaign," *Nicotine & Tobacco Research*, 220 (5), pp. 543–551.
[16] Vallone et al. (2017), op. cit.
[17] Formally, brand equity refers to the differential effect of brand knowledge on consumer response to the marketing of the brand. Brand-equity measures typically include a set of positive and negative brand attributes that are linked to a brand name and symbol. In the Vallone et al. (2017) study, brand equity was measured on four theory-derived dimensions of brand loyalty, leadership/popularity, brand personality, and brand awareness. *See also* Keller, K.L. (2002), *Branding and Brand Equity*, Cambridge, MA: MSI.

like those used by truth, must evolve to stay relevant with a target audience. Findings from this study highlight the need for health-related messages to be culturally relevant, particularly those focused on shaping the health behaviors of youth and young adults."[18]

Holtgrave et al. (2009) examined the cost effectiveness of *truth*'s social marketing campaign for the period 2000-2002.[19] Total expenditure during 2000–2002 to develop, deliver and evaluate the *truth* campaign totaled just over $324 million. The authors estimated that the campaign recouped its costs, concluding that: "*This study suggests that the truth campaign not only markedly improved the public's health but did so in an economically efficient manner.*"

B. CDC's *Tips From Former Smokers* (2012–present)

Background and description of the campaign

Since 2012, the CDC has annually implemented a federally funded, national mass media tobacco education campaign—*Tips From Former Smokers* ("*Tips*")—using TV, websites, radio, magazines, and social media. *Tips* consists of antismoking advertisements that feature former cigarette smokers discussing their personal stories of living with serious long-term health consequences from smoking and secondhand smoke exposure. The primary target segment is smokers aged 18–54 years. The secondary target segment is family members, health care providers, and faith communities who can help reach smokers. *Tips*' campaign goals include, among other things, building public awareness of the immediate health damage caused by smoking and exposure to secondhand smoke.[20]

Results

In an article funded by the CDC, McAfee et al. (2013) evaluated the initial, 2012 *Tips* campaign that lasted from March 19 through June 10, 2012.[21] Ad recall was 78% among smokers and 74% among nonsmokers.

Neff et al. (2016) conducted an analysis of the 2014 *Tips* campaign. The results confirmed the effectiveness of *Tips* reported by McAfee et al. (2013) for another campaign year. Seventy-nine percent of smokers recalled having seen at least one TV advertisement from the 2014 campaign.

C. FDA's *The Real Cost* Campaign (2014–present)

Background and description of the campaign

Since 2014, the FDA has run *The Real Cost* campaign. *Real Cost* is focused on youth between 12 and 17 years of age who are at higher risk of becoming smokers, like those who have already tried cigarettes or who are likely to experiment. *Real Cost* messages have appeared on national TV,

---

[18] Vallone et al. (2017), op. cit., p. 8.

[19] Holtgrave, D.R. et al. (2009), "Cost–Utility Analysis of the National truth® Campaign to Prevent Youth Smoking," *American Journal of Preventive Medicine*, 35 (5), pp. 385–388.

[20] Prochaska, J.J. (2019), "The 2016 Tips From Former Smokers® Campaign: Associations With Quit Intentions and Quit Attempts Among Smokers With and Without Mental Health Conditions," *Nicotine & Tobacco Research*, 21 (5), pp. 576–583. Description of "Tips" taken from this article, p. 577. *Tips* receives its funding through from the 2010 Affordable Care Act.

[21] McAfee, T. et al. (2013), "Effect of the First Federally Funded US Antismoking National Media Campaign," *The Lancet*, 382 (9909), pp. 2003-2011.

radio, the Internet, and out-of-home displays, as well as in magazines and movie theaters. The central theme of the campaign is: "Every cigarette costs you something." The campaign focused on two facets of smoking: loss of control due to addiction and the cosmetic effects of smoking. The resulting ads focused on teens missing time with friends because they needed to smoke and demonstrated how smoking can affect one's skin or teeth. The FDA works on this campaign with Foote, Cone & Belding, which is one of the largest global advertising agency networks. From 2014 to 2016, the campaign focused on anti-smoking initiatives. In 2016, the campaign was expanded to combat chewing tobacco, and in 2018, it was further expanded to e-cigarette prevention.[22]

Results

Duke et al. (2015) conducted a nationally representative longitudinal study among U.S. youth to examine campaign awareness levels and evaluate the effect of *The Real Cost* on smoking-related beliefs and behaviors and found that over 90% of the campaign's target audience (susceptible nonsmokers and experimenters) were aware of at least one advertisement 6 to 8 months after campaign launch. Most surveyed youth considered advertisements to be effective based on assessments of perceived effectiveness.[23]

A second study by Duke et al. (2018) focused on changes in campaign-targeted beliefs, 14 months after the start of the campaign. The authors found that agreement with the eight campaign-targeted beliefs increased 11.5% from baseline measurement, and campaign exposure was associated with increased odds of agreeing with campaign-targeted beliefs. The authors concluded: "*A sustained national tobacco public education campaign can change population-level perceptions of tobacco-related harms among youth.*"[24]

Just four days after FDA's proposed graphic health warning ruling was published, acting FDA Commissioner Ned Sharpless commented that "*[s]ince 'The Real Cost' launched in 2014, it has reached up to 95% of its target U.S. youth audience aged 12–17 with thousands of messages through TV, digital, social, outdoor and radio programs. More than 21.9 million youth have spent time on TheRealCost.gov since its launch in 2014 and 31.6 million youth have engaged with the FDA on social media*." Moreover, he commented that the Real Cost Campaign was successful in communicating with the more than 10 million at-risk teens in the U.S. about the harmful effects of cigarette smoking, saving $180 for every dollar of the nearly $250 million invested in the campaign. And he asserted that "*our award-winning campaign has prevented up to 587,000 youth nationwide from initiating smoking*."[25]

---

[22] https://www.mmm-online.com/home/channel/campaigns/study-fda-anti-tobacco-campaign-prevented-350000-teens-from-smoking/.

[23] Duke, J.C. (2015), " Youth's Awareness of and Reactions to The Real Cost National Tobacco Public Education Campaign," *PloS One*, December 17, 10(12), pp. 1–12.

[24] Duke, J.C. (2018), "Effect of a National Tobacco Public Education Campaign on Youth's Risk Perceptions and Beliefs About Smoking," *American Journal of Health Promotion*, 32 (5), pp. 1248–1256

[25] https://www.morningstar.com/news/pr-newswire/20190820ph46901/statement-from-acting-fda-commissioner-ned-sharpless-md-on-new-results-demonstrating-continued-success-of-the-agencys-youth-smoking-prevention-efforts-and-significant-public-health-cost-savings.

D. FDA's *Fresh Empire* (2015–present)

Background and description of the campaign[26]

The *Fresh Empire* campaign seeks to prevent and reduce tobacco use among at-risk multicultural adolescents aged 12–17 who identify with hip-hop culture, specifically African American, Hispanic, and Asian American/Pacific Islander youth. The target audience was developed using a segmentation approach that focuses on youth who share the same core ideals, have similar life experiences and common interests, and are at higher risk for tobacco use.

The campaign's key message is "Keep it Fresh: Live Tobacco Free." *Fresh Empire* encourages hip-hop youth to reach their goals of being successful, attractive, and in control through a tagline emphasizing that living tobacco-free will help them achieve their idealized self-image. Messages aim to:

- Position tobacco addiction as an obstacle preventing youth from being fully in control of their life.
- Communicate that the mix of chemicals found in cigarettes can cause negative, long-term health consequences as well as cause immediate damage.
- Address how the negative health consequences of smoking cigarettes can affect youth and those around them.

The campaign associates living tobacco-free with desirable hip-hop lifestyles through a variety of interactive marketing tactics including the use of traditional paid media, engagement through multiple digital platforms, and outreach at the local level. The campaign utilizes TV, radio, and print advertising; print and digital communications, including social media, and live events.

Results

Fresh Empire messages have won a series of awards, including:

- **Hermes Awards**[27]
  - 2018 Platinum: Event Marketing category
  - 2018 Gold: Website Overall – Government category
  - 2018 Honorable Mention: Game or Contest category

- **Telly Awards**[28]
  - 2018 Bronze: "Motivational for Online" category for the *Keep It Moving Forward The Scale* series
  - 2018 Bronze: "Campaign: Social Responsibility for Branded Content" category for *The New Wave* series
  - 2017 Silver: "Motivational" category for Video/Shows/Segments
  - 2017 Bronze: "Public Interest & Awareness Promotional Pieces" category

---

[26] Taken from https://www.fda.gov/tobacco-products/public-health-education-campaigns/fresh-empire-campaign.

[27] The Hermes Awards are an international competition for creative professionals involved in the concept, writing and design of traditional materials, marketing and communication programs, and emerging technologies. https://hermesawards.com/

[28] The Telly Awards honor the finest film and video productions, groundbreaking web commercials, videos and films, and outstanding local, regional, and cable TV commercials and programs from around the world. The Telly Awards recognize winners with Silver and Bronze awards. https://www.icf.com/news/2016/09/won-16-telly-awards.

- **2017 Association of National Advertisers (ANA),** Winner, Multicultural Excellence Awards, Experiential category

- **Shorty Social Good Awards**[29]
  - 2017 finalist in the Instagram category
  - 2016 finalist in the Public Health category

These Awards show that *Fresh Empire*'s social marketing messages are well designed, creative, and impactful. The FDA has set up a longitudinal evaluation study to assess the efficacy of the campaign but the results of that study are not yet available.[30]

E. FDA's *This Free Life* (2016–present)

Background and description of the campaign[31]
In 2016, the FDA initiated the *This Free Life* campaign, which is aimed at preventing and reducing tobacco use among lesbian, gay, bisexual, and transgender (LGBT) young adults (18–24 years). This group is nearly twice as likely to use tobacco as other young adults. The campaign seeks to reach the target segment through multiple channels including social media and LGBT-specific digital sites, streaming radio, LGBT print media, branded promotions at LGBT events and social venues, and signage at bus stops in areas where LGBT young adults are likely to socialize.

This Free Life is designed to appeal to the shared values, similar life experiences, and common interests of LGBT young adults. The essence of the campaign is expressed through its tagline: "Freedom to Be, Tobacco-Free." Key messages focus on:

- The negative health consequences and addiction risks of tobacco use;
- The dangerous mix of chemicals found in cigarette smoke; and
- How tobacco use negatively affects aspects of life that are very important to LGBT young adults while a tobacco-free lifestyle aligns with LGBT ideals.

Results
This Free Life has already won a series awards:

- **Hermes Awards**
  - 2018 Platinum: Social Marketing Campaign category
  - 2018 Platinum: Social Video category
  - 2018 Platinum: YouTube Video category

- **Telly Awards**
  - 2018 Gold: "Public Interest & Awareness for Online" category for the Tip the Scale series

---

[29] The Shorty Social Goods Awards is an awards program created to raise global awareness around the positive impact brands, agencies, and nonprofits can have on society. https://shortyawards.com/socialgood.

[30] https://www.fda.gov/consumers/consumer-updates/fdas-smoking-prevention-campaigns-reaching-teens-where-they-live.

[31] Taken from https://www.fda.gov/tobacco-products/public-health-education-campaigns/free-life-campaign.

- 2018 Bronze: "Lighting for Branded Content" category for the Tip the Scale series
- 2018 Bronze: "Public Service and Activism for Social Video" category for The Flawless Experiment
- 2017 Bronze: Cultural category for Video/Shows/Segments

- **Ad Pop Awards 2017**
  - Gold: Non-Profit category for print ads

- **Shorty Social Good Awards**
  - 2017 Finalist: Tumblr category

- **Association of National Advertisers (ANA)**
  - 2017 Winner: Multicultural Excellence Award LGBT category
  - 2016 Grand Prize: Multicultural Excellence Award

These Awards show that *This Free Life* social marketing messages are well designed, creative, and impactful. FDA has tasked Center for Tobacco Products (CTP) with evaluating the effectiveness of the campaign. Results of that study are not yet available.[32]

F. FDA's Every Try Counts (2018–present)

Background and description of the campaign

In 2017, the FDA launched the *Every Try Counts* campaign. The goals of this campaign are to change attitudes and beliefs about what it means to quit smoking, increase motivation to try quitting again, and encourage smokers to 'practice the quit,' as each attempt makes them more likely to succeed. The target segment is adult smokers, aged 25–54 years. In terms of advertisement placement, it focuses on gas stations or convenience stores—retail locations that typically feature cigarette advertisements.

Results

The FDA plans to carry out a longitudinal multi-year study to evaluate the effectiveness of the campaign. Results of that study are not yet available.[33]

3.3. Synthesis of Research on Anti-Smoking Social Marketing Campaigns Targeting Youth

The campaigns discussed above demonstrate how social marketing has been effectively employed by the FDA and other public health entities to target particular segments of the population. Adolescents are the primary target segment for three of the major national social marketing campaigns discussed above, viz., Truth Initiative's *truth*® campaign, and the FDA's *The Real Cost* and *Fresh Empire* campaigns. Other campaigns have effectively targeted other demographics, as

---

[32] https://www.fda.gov/tobacco-products/research/research-and-evaluation-survey-public-education-campaign-tobacco-among-lgbt-respect-lgbt.

[33] https://www.fda.gov/consumers/consumer-updates/fdas-smoking-prevention-campaigns-reaching-teens-where-they-live.

format. Of course, tone and format need to be aligned with content, but the same basic content can be conveyed in different ways.

Message tone

Regarding message tone, the social marketer has to decide whether to adopt a positive tone, generating positive emotions such as humor or happiness (e.g., how not smoking makes you more successful when looking for a date) or negative emotions such as sadness or fear (e.g., how smoking can lead to cancer).

The intensity of emotions is also important, especially if a negative emotion like fear is used. If fear arousal is very high, message effectiveness declines because it produces inhibiting effects—the receiver may emotionally block the message by tuning out, perceiving it selectively, or denying its arguments outright.[48] Research has shown that anti-smoking messages and graphic health warnings using high levels of fear were ineffective because they led to defensive tendencies such as message avoidance and interfered with the processing of recommended solutions.[49] These findings highlight that the effectiveness of fear-based warnings, such as proposed by the FDA, is questionable.

Message format

The message format has to also be modified to the target audience to be effective. Youth are more likely to recall and think about advertising when executions include, *inter alia*, personal testimonials, a surprising narrative, sound, and editing.[50] This may also apply to young adults, but it is unclear whether these would work equally with older groups. In short, it is clear that a one-size fits all approach like the one taken by the FDA in its proposed graphic health warnings is neither a sensible nor effective way to communicate across different target populations.

Message source (from whom?)

Research has shown that messages delivered by a credible source achieve higher believability and recall.[51] The three most often identified sources of message credibility are expertise, trustworthiness, and likability. Expertise is the specialized knowledge the communicator possesses to back the claim. Can the communicator make valid claims? Trustworthiness describes how objective and honest the source is perceived to be. For example, friends or *Consumer Reports* are seen as more trustworthy than salespeople, and people who are not paid to endorse a product are viewed as more trustworthy than paid endorsers.[52] Likability refers to the source's attractiveness.

---

[48] Sternthal, B., and C.S. Craig (1974), "Fear Appeals: Revisited and Revised," *Journal of Consumer Research*, 1 (December), pp. 22-34.

[49] Steenkamp, JBEM, H. Baumgartner, and E. Van der Wulp (1996), "Arousal Potential, Arousal, Stimulus Attractiveness, and the Moderating Role of Need for Stimulation," *International Journal of Research in Marketing*, 13 (4), pp. 319-329. Steenkamp et al. found evidence for an inverted-U (low fear and high fear led to lower appreciation of the message) for a series of seven social marketing ads, of which five were anti-smoking ads; Kok et al. (2018) "Ignoring Theory and Misinterpreting Evidence: The False Belief in Fear Appeals," *Health Psychology Review*, 12 (2), 111-125; see also Keller, P.A. and L.G. Block (1996), "Increasing the Persuasiveness of Fear Appeals: The Effect of Arousal and Elaboration," *Journal of Consumer Research*, 22 (March), pp. 448-459.

[50] Allen op. cit., p. e73.

[51] Belch, G.E. and M.A. Belch (2012), *Advertising and Promotion: An Integrated Marketing Communications Perspective*, New York: McGraw-Hill/Irwin, 9th edition, pp. 181-196.

[52] Kotler and Keller, op. cit., p. 568.

A reason why personal testimonials by ex-smokers are so effective is that they have high credibility. While they may not be medical doctors, as ex-smokers, they do have expertise about the consequences of smoking. They are trustworthy as they do not have an obvious benefit to participate in the campaign (unless the target audience believes they are paid to tell a sad story). They are also people like the target audience, which enhances their likability. This assumes that the testimonial is given by a person with whom the target audience can identify. For example, it will be more effective in terms of source credibility if an LGBT person gives a testimonial in *This Free Life* campaign, which is targeting the LGBT community, than if a straight person is used in this campaign.

Celebrities are often used in marketing campaigns because they are (often) likable and may be seen as trustworthy.[53] Social marketers understand this too, and have used them in their campaigns. For example, Katie Couric is known for her support for colon cancer screening after her husband passed away because of the disease. Maria Shriver has been an advocate for Alzheimer's awareness and research since her father was diagnosed with the disease in 2003. CDC used Christy Turlington in an ad in which she discusses the consequences of losing her father to smoking-related illness.

All this indicates that message content and execution should vary by target segment. A one message-fits-all approach, such as with the FDA's proposed graphic health warnings, is less effective than adapting the message content and tone to the characteristics of the target audience. Social marketing campaigns are superior to graphic health warnings on these aspects since the former can be segment specific, as various campaigns of the FDA such as *Fresh Empire* and *This Free Life,* among others, clearly show.

4.4. Step 4: Select the communication channels

Social marketers must select communication channels through which the communication will be delivered to the target audience. Effective social marketing uses a variety of channels because different target segments have different media preferences (e.g., young people watch YouTube more often than older people, while the reverse applies to TV). For example, the *truth* campaign utilizes TV commercials, websites, radio ads, and social media (#FinishIt).

Communication channel decisions are guided by several considerations including fit with the target audience (i.e., aligning communication channels with the target audience profile and media habits), channel reach (i.e., the percentage of people in the target audience who are exposed to the ad campaign during a given period of time), and media mix (i.e., using multiple communication channel platforms—including personal (i.e., face-to-face) and nonpersonal (mass) communication channels[54]—to increase reach and campaign effectiveness.[55] For example the FDA's *This Free Life* campaign, whose target segment is LGBT young adults (18–24), effectively aligns communication channels with the target audience profile and media habits. The campaign seeks

[53] Belch and Belch, op. cit., pp. 182-187.
[54] Kotler and Keller, op. cit., pp. 568-570.
[55] Danaher, P. and T.S. Dagger (2013), "Comparing the Relative Effectiveness of Advertising Channels: A Case Study of a Multimedia Blitz Campaign," *Journal of Marketing Research*, 50 (August), pp. 517-534.

Exhibit E

NERA Survey: Consumer Perceptions of Cigarette Warning Labels

Submitted by:

Samantha Iyengar, Ph.D.
October 8, 2019

23. After viewing a random selection of 5 of the 13 proposed images, respondents were asked for each image "[b]efore today, had you heard about this smoking-related health effect described in the warning?" The results were analyzed to calculate a proportion of responses indicating that respondents had not heard about the smoking-related health effect prior to viewing a specific warning in the respective survey condition. A two-sample test of proportions[17] was used to determine whether there are statistically significant differences in the proportion of respondents in the respective text only and text + graphics conditions compared to the condition in which respondents were shown text and graphics on 50 percent of the top front and back of the pack.[18]

24. Overall, there are very few statistically significant differences in the proportion of respondents who reported that they had not heard about the smoking-related health effect prior to viewing the proposed warnings. There were no statistically significant differences in the proportion of respondents who reported that they had not heard about the smoking-related health effect prior to viewing any of the proposed warnings in the text + graphics 50 percent front and back condition compared to the same warnings shown as (1) text only on the side of the pack, (2) text + graphics on the side of the pack, or (3) text + graphics on the top 20 percent of the front of the pack.

25. Moreover, there were very few statistically significant differences in the proportion of respondents who reported that they had not heard about the smoking-related health effect prior to viewing the majority of the proposed warnings in the text + graphics 50 percent front and back condition compared to the same warnings shown as (1) text only on the top 50 percent of the front of the pack (no statistically significant difference for 12 of 13 warnings) or (2) text only on the top 20 percent of the pack (no statistically significant difference for 11 of 13 warnings). These results are summarized in **Table 2** below and included in **Appendix 3**.

---

[17] $z = \frac{\text{observed difference - expected difference}}{\text{SE [standard error] for difference}}$ *See* Freedman et al. 2007, pp. 505-506.

[18] This condition was used as the comparison because the FDA website provides a sample pack with the warnings that depicts the same warning on both the front and back of the packs. https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warnings.

Table 2. Summary of Statistical Tests
Comparing Text + Graphics, 50% Front and Back versus Other Study Conditions

Comparing the proportion of respondents who reported that they had not heard about the smoking-related health effect prior to viewing any of the proposed warnings.

Condition	Results
Text Only, side of pack	No statistically significant differences for any warning
Text + Graphics, side of pack	No statistically significant differences for any warning
Text + Graphics, top 20%	No statistically significant differences for any warning
Text Only, Top 50%	No statistically significant difference for 12 of 13 warnings
Text Only, Top 20%	No statistically significant difference for 11 of 13 warnings

26. Respondents were asked "[b]ased on the warnings you just saw, please tell us whether you agree or disagree with each of the following statements." The results were analyzed to calculate the proportion of respondents who agreed with each of the smoking-related health effect statements presented in the warnings. A two-sample test of proportions[19] was used to determine whether there are statistically significant differences in the proportion of respondents in the respective text only and text + graphics conditions compared to the condition in which respondents were shown text and graphics on 50 percent of the top front and back of the pack.[20]

27. Overall, there are few statistically significant differences in the proportion of respondents who indicated that they agree with the smoking-related health effect statements presented in the warnings. There were no statistically significant differences in the proportion of respondents who indicated that they agree with the smoking-related health effect statements presented in the warnings in the text + graphics 50 percent front and back condition compared to the same warnings shown as text + graphics on the side of the pack.

28. Moreover, there were few statistically significant differences in the proportion of respondents who indicated that they agree with the smoking-related health effect statements presented in the warnings in the text + graphics 50 percent front and back condition compared to the same warnings shown as (1) text + graphics on the top 20 percent of the pack (no statistically significant difference for 12 of 13 warnings), (2) text only on the top 50 percent of the front of the pack (no statistically significant

[19] $z = \frac{\text{observed difference - expected difference}}{\text{SE [standard error] for difference}}$ *See* Freedman et al. 2007, pp. 505-506.

[20] This condition was used as the comparison because the FDA website provides a sample pack with the warnings that depicts the same warning on both the front and back of the packs. https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warnings.

difference for 11 of 13 warnings), (3) text only on the side of the pack (no statistically significant difference for 10 of 13 warnings), or (4) text only on the top 20 percent of the front of the pack (no statistically significant difference for 9 of 13 warnings). These results are summarized in **Table 3** below and included in **Appendix 3**.

Table 3. Summary of Statistical Tests
Comparing Text + Graphics, 50% Front and Back versus Other Study Conditions

Comparing the proportion of respondents who indicated that they agree with the smoking-related health effect statements presented in the warnings.

Condition	Results
Text + Graphics, side of pack	No statistically significant differences for any warning
Text + Graphics, top 20%	No statistically significant difference for 12 of 13 warnings
Text Only, Top 50%	No statistically significant difference for 11 of 13 warnings
Text Only, side of pack	No statistically significant difference for 10 of 13 warnings
Text Only, Top 20%	No statistically significant difference for 9 of 13 warnings

29. Respondents were asked "If you have an opinion, do you think that any of the [images used in the] warnings are trying to make people feel afraid?". In response to this question, 86 percent of respondents who viewed the image with text and graphics on 50 percent of the front and back label said that they believe the warnings are trying to make people feel afraid. Likewise, when asked "If you have an opinion, do you think that any of the [images used in the] warnings are trying to make people feel disgusted?", 68 percent indicated that they believe the warnings are trying to make people feel disgusted. Similarly, when asked "If you have an opinion, do you think that any of the [images used in the] warnings are trying to shock people?", 85 percent of this group indicated that they believe the warnings are trying to shock people, and finally, when asked "If you have an opinion, do you think that any of [images used in the] warnings are trying to make people feel distress?", 70 percent of this group indicated that the warnings are trying to make people feel distress.[21] These results are included in **Appendix 3**.

30. Current smokers were asked a series of questions regarding whether or not each of the respective warnings conveys any behavioral imperative about smoking and/or purchasing the product.[22] These questions are shown below.

[21] These questions were asked in random order. Response options a and b were randomly rotated. Questions asked of respondents who viewed the proposed graphic warning labels included the bracketed words.
[22] The order of these questions was randomly rotated for each respondent. The respective questions were repeated (one at a time) for each of the assigned images. Response options a, b and c were randomly rotated.

If you have an opinion, does the warning on this image convey …?
a. The warning conveys that you SHOULD smoke this product
b. The warning conveys that you should NOT smoke this product
c. The warning does not convey anything about whether or not to smoke this product
d. Don't know / unsure
e. Prefer not to say

If you have an opinion, does the warning on this image convey …?
a. The warning conveys that you SHOULD purchase this product
b. The warning conveys that you should NOT purchase this product
c. The warning does not convey anything about whether or not to purchase this product
d. Don't know / unsure
e. Prefer not to say

31. In response to these questions, overall, 74 percent of current smokers indicated that the warnings convey a message that they should NOT smoke this product. Likewise, overall, 71 percent of this group indicated that the warnings convey that they should NOT purchase this product. These results are included in **Appendix 3**.

IV. Conclusions

32. My opinions and conclusions as expressed in this report are to a reasonable degree of professional certainty based on the survey described in this report.

Respectfully submitted,

Samantha Iyengar, Ph.D.

NERA Economic Consulting
1166 Avenue of the Americas, 24th Floor
New York, NY 10036

October 8, 2019

Appendix 3

Appendix 3_1
Survey Data Counts, By Condition

Before today, had you heard about this smoking-related health effect described in the warning?

Percent Responding "No" [1]

	Top 50%		**Side of Pack**								**Top 50%**				**Top 20%**							
	(a)		**(b)**				**(c)**				**(d)**				**(e)**				**(f)**			
	Text + Graphics, Front & Back		Text Only		(a) - (b)		Text + Graphics		(a) - (c)		Text Only		(a) - (d)		Text Only		(a) - (e)		Text + Graphics		(a) - (f)	
Stimuli	N [3]	%	N [3]	%	%	p	N [3]	%	%	p	N [3]	%	%	p	N [3]	%	%	p	N [3]	%	%	p
Tobacco smoke can harm your children.	148	18.9	158	15.2	3.7	0.385	145	11.7	7.2	0.088	154	10.4	**8.5**	**0.036***	158	9.5	**9.4**	**0.018***	145	13.8	5.1	0.236
Smoking during pregnancy stunts fetal growth.	148	20.9	160	14.4	6.6	0.130	148	15.5	5.4	0.229	154	16.9	4.1	0.367	158	8.9	**12.1**	**0.003***	139	15.8	5.1	0.264
Smoking causes age-related macular degeneration which can lead to blindness.	149	61.1	159	58.5	2.6	0.644	147	63.9	(2.9)	0.610	150	60.0	1.1	0.849	157	55.4	5.7	0.316	146	61.0	0.1	0.984
Smoking causes bladder cancer, which can lead to bloody urine.	149	65.1	157	67.5	(2.4)	0.655	144	66.7	(1.6)	0.777	150	61.3	3.8	0.499	159	70.4	(5.3)	0.316	146	65.1	0.0	0.995
Smoking reduces blood flow to the limbs, which can require amputation.	147	62.6	160	52.5	10.1	0.074	142	54.2	8.4	0.149	157	54.1	8.4	0.136	159	52.8	9.8	0.085	150	54.0	8.6	0.134
Smoking causes cataracts, which can lead to blindness.	145	60.7	159	62.3	(1.6)	0.778	145	59.3	1.4	0.811	151	66.2	(5.5)	0.323	163	62.6	(1.9)	0.734	142	62.0	(1.3)	0.824
Smoking causes COPD, a lung disease that can be fatal.[2]	-	-	157	17.8	-	-	-	-	-	-	151	23.8	-	-	162	12.3	-	-	-	-	-	-
Smoking causes COPD, a lung disease that can be fatal. (Image of lungs)	150	15.3	-	-	(2.5)	0.556	144	13.9	1.4	0.726	-	-	(8.5)	0.063	-	-	3.0	0.444	146	11.6	3.7	0.353
Smoking causes COPD, a lung disease that can be fatal. (Image of man)	148	16.2	-	-	(1.6)	0.707	142	16.9	(0.7)	0.875	-	-	(7.6)	0.100	-	-	3.9	0.329	148	11.5	4.7	0.239
Smoking can cause heart disease and strokes by clogging arteries.	148	20.9	152	26.3	(5.4)	0.274	147	22.4	(1.5)	0.754	154	21.4	(0.5)	0.918	162	24.1	(3.1)	0.511	141	19.1	1.8	0.703
Smoking causes head and neck cancer.	151	51.7	163	48.5	3.2	0.572	143	49.7	2.0	0.731	151	51.7	0.0	1.000	156	52.6	(0.9)	0.873	142	59.9	(8.2)	0.158
Smoking causes type 2 diabetes, which raises blood sugar.	146	59.6	159	67.9	(8.3)	0.130	144	59.0	0.6	0.923	155	65.2	(5.6)	0.318	159	61.0	(1.4)	0.800	146	67.1	(7.5)	0.182
Tobacco smoke causes fatal lung disease in nonsmokers.	145	16.6	159	13.8	2.7	0.509	144	16.0	0.6	0.894	156	19.9	(3.3)	0.456	159	17.6	(1.1)	0.807	142	19.0	(2.5)	0.585
Smoking reduces blood flow, which can cause erectile dysfunction.	146	56.2	157	56.7	(0.5)	0.927	145	49.7	6.5	0.266	147	59.2	(3.0)	0.601	158	51.3	4.9	0.392	142	54.9	1.2	0.833

Notes:

*** indicates statistically significant difference (p-value less than 0.05).**

[1] Percentages are calculated as the proportion of responses to a specific stimulus within each respective condition.

[2] Text + Graphics conditions (a, c, and f) broke out the statement, "Smoking causes COPD, a lung disease that can be fatal," into two stimuli because FDA proposed graphic warnings use the same statement with two images. Because respondents in the Text Only conditions (b, d, and e) saw only the text statement, the single percentage in the comparative condition for the related statement was used to calculate the differences for both stimuli in the comparison condition (a).

[3] Equals the total number of participants shown a specific stimulus within the respective condition.

Appendix 3_2
Survey Data Counts, By Condition

Based on the warnings you just saw, please tell us whether you agree or disagree with each of the following statements.

Percent Responding "Agree" [1]

	Top 50%		**Side of Pack**								**Top 50%**				**Top 20%**							
	(a)		**(b)**				**(c)**				**(d)**				**(e)**				**(f)**			
	Text + Graphics, Front & Back		Text Only		(a) - (b)		Text + Graphics		(a) - (c)		Text Only		(a) - (d)		Text Only		(a) - (e)		Text + Graphics		(a) - (f)	
Stimuli	N [2]	%	N [2]	%	%	p	N [2]	%	%	p	N [2]	%	%	p	N [2]	%	%	p	N [2]	%	%	p
Tobacco smoke can harm your children.	148	91.2	158	93.0	(1.8)	0.554	145	91.7	(0.5)	0.876	154	87.7	3.6	0.316	158	98.1	**(6.9)**	**0.007***	145	91.7	(0.5)	0.876
Smoking during pregnancy stunts fetal growth.	148	91.2	160	86.3	5.0	0.170	148	84.5	6.8	0.075	154	88.3	2.9	0.406	158	86.1	5.1	0.158	139	89.9	1.3	0.709
Smoking causes age-related macular degeneration which can lead to blindness.	149	76.5	159	68.6	8.0	0.118	147	66.7	9.8	0.060	150	76.7	(0.2)	0.974	157	69.4	7.1	0.164	146	73.3	3.2	0.523
Smoking causes bladder cancer, which can lead to bloody urine.	149	76.5	157	67.5	9.0	0.080	144	75.0	1.5	0.763	150	70.7	5.8	0.252	159	71.1	5.4	0.278	146	74.7	1.9	0.711
Smoking reduces blood flow to the limbs, which can require amputation.	147	77.6	160	67.5	**10.1**	**0.049***	142	76.8	0.8	0.873	157	71.3	6.2	0.215	159	73.0	4.6	0.353	150	78.7	(1.1)	0.816
Smoking causes cataracts, which can lead to blindness.	145	77.9	159	67.3	**10.6**	**0.038***	145	73.1	4.8	0.339	151	66.2	**11.7**	**0.025***	163	66.9	**11.1**	**0.031***	142	69.0	8.9	0.087
Smoking causes COPD, a lung disease that can be fatal.[3]	-	-	157	90.4	-	-	-	-	-	-	151	84.8	-	-	162	92.6	-	-	-	-	-	-
Smoking causes COPD, a lung disease that can be fatal. (Image of lungs)	150	91.3	-	-	0.9	0.787	144	91.0	0.4	0.913	-	-	6.6	0.079	-	-	(1.3)	0.682	146	89.0	2.3	0.507
Smoking causes COPD, a lung disease that can be fatal. (Image of man)	148	89.2	-	-	(1.3)	0.717	142	95.1	(5.9)	0.064	-	-	4.4	0.256	-	-	(3.4)	0.296	148	90.5	(1.4)	0.700
Smoking can cause heart disease and strokes by clogging arteries.	148	86.5	152	80.3	6.2	0.148	147	89.8	(3.3)	0.379	154	83.8	2.7	0.507	162	83.3	3.2	0.439	141	85.1	1.4	0.737
Smoking causes head and neck cancer.	151	80.8	163	71.8	9.0	0.061	143	77.6	3.2	0.503	151	72.8	7.9	0.102	156	73.1	7.7	0.109	142	76.1	4.7	0.324
Smoking causes type 2 diabetes, which raises blood sugar.	146	76.0	159	62.3	**13.8**	**0.010***	144	70.1	5.9	0.258	155	70.3	5.7	0.265	159	65.4	**10.6**	**0.042***	146	69.2	6.8	0.189
Tobacco smoke causes fatal lung disease in nonsmokers.	145	86.9	159	83.6	3.2	0.426	144	80.6	6.3	0.144	156	77.6	**9.3**	**0.035***	159	84.3	2.6	0.517	142	84.5	2.4	0.563
Smoking reduces blood flow, which can cause erectile dysfunction.	146	82.2	157	74.5	7.7	0.106	145	73.8	8.4	0.084	147	74.1	8.0	0.096	158	70.3	**11.9**	**0.015***	142	69.0	**13.2**	**0.009***

Notes:

*** indicates statistically significant difference (p-value less than 0.05).**

[1] Percentages are calculated as the proportion of responses to a specific stimulus within the respective condition. The analysis is limited to responses from participants who viewed stimuli corresponding to the respective warnings..

[2] Equals the total number of participants shown a specific stimulus within the respective condition.

[3] Text + Graphics conditions (a, c, and f) broke out the statement, "Smoking causes COPD, a lung disease that can be fatal," into two stimuli because FDA proposed graphic warnings use the same statement with two images.
Because respondents in the Text Only conditions (b, d, and e) saw only the text statement, the single percentage in the comparative condition for the related statement was used to calculate the differences for both stimuli in the comparison condition (a).

Appendix 3_3
Condition: Text and Graphics, top 50% pack front and back
Share of Respondents Who Answered "Yes"

Question	Share (%)[1] (N = 384)
If you have an opinion, do you think that any of [the images used in] the warnings are trying to make people feel afraid?	85.9 %
If you have an opinion, do you think that any of [the images used in] the warnings are trying to make people feel disgusted?	68.2 %
If you have an opinion, do you think that any of [the images used in] the warnings are trying to shock people?	85.4 %
If you have an opinion, do you think that any of [the images used in] the warnings are trying to make people feel distress?	70.3 %

Notes

[1] Represents the share of respondents who answered "Yes" when asked the respective question. Response options included:

a. Yes
b. No
c. Don't know / unsure
d. Prefer not to say

The order of these questions was randomly rotated for each respondent. Response options a and b were randomly rotated. Questions asked of respondents who viewed the proposed graphic warning labels included the bracketed words.

Appendix 3_4
Condition: Text and Graphics, Top 50% of Pack Front and Back

Question	Should Not[1] (N = 192)
Message conveyed by the warning about whether or not to *smoke* the product	74.5 %
Message conveyed by the warning about whether or not to *purchase* the product	68.2 %

Notes:

[1] Represents the overall share of current smokers who responded, "The warning conveys that you should NOT [*smoke* | *purchase*] this product when asked, "If you have an opinion, does the warning on this image convey …?" Response options included:

a. The warning conveys that you SHOULD [*smoke* | *purchase*] this product
b. The warning conveys that you should NOT [*smoke* | *purchase*] this product
c. The warning does not convey anything about whether or not to [*smoke* | *purchase*] this product
d. Don't know / unsure
e. Prefer not to say

These questions were only asked of respondents who indicated that they are current smokers (defined as those who smoke every day or some days, and 100+ lifetime cigarettes). The order of the questions was randomly rotated for each respondent. The respective questions were repeated (one at a time) for each of the assigned images. Response options a, b and c were randomly rotated.

Exhibit F

Report of

Dr. John E. Martin, Ph.D.

September 30, 2019

to keep moving forward; and Maintenance – a sustained behavior change (defined as more than 6 months) with an intent to maintain the behavior change going forward. Unfortunately, campaigns that rely on a broad-based effort, ignoring or opposing motivation science approaches, fail to recognize or work within and through those many smokers arrayed throughout the key stages of readiness for, contemplation of, and experimenting with change.

Importantly, and according to one major study, Pre-contemplators make up the largest segment of smokers (Wewers 2003). In their study, cross-sectional data were collected from an average of 35,000 daily smokers who responded to the Current Population Survey (CPS) in three time periods during the 1990's. The study found that nearly 60 percent of respondents were in the pre-contemplation stage and only 7.7% were in the preparation or experimenting ("testing the waters"). Most notably, pre-contemplators tend to have the lowest self-efficacy (Levesque 2006). According to the FDA, there are approximately 34.3 million U.S. adult smokers and nearly 1.4 million U.S. youth smokers. Thus, such a large population of smokers will undoubtedly include a majority of smokers in the pre-contemplation stage with low self-efficacy, who will be harmed, such as pushing them farther way from any readiness or willingness to attempt quitting, by the warnings proposed by the FDA.

Physiological Research

Neuroscience supports the behavioral research showing that smokers have a strong tendency to avoid high-threat messages. Researchers studied the response to pictures and messages depicting the negative health consequences of smoking. (Kessels, Ruiter, Brug, & Jansma, 2010). The high-threat messages included pictures of black lungs, children near smoking cigarettes, skeletons with a smoking cigarette, and other images illustrating the negative health consequences of smoking. The researchers looked at the response to threatening health commercials by recording event-related potentials (ERPs), which are a type of electrical activity in the brain measured by EEG, in response to a specific event or stimulus. The study found that threatening health information caused less attention holding among smokers for whom the health threat is self-relevant. Another study looked at response allocation to threatening health commercials regarding the negative health effects of smoking (Kessels 2014). Smokers reacted faster to a noise while watching high-threat versus low-threat anti-smoking commercials, meaning they avoided the more threatening message more quickly.

Youth Smokers Negatively Reactive to Pressure

Youth, a primary focus of the FDA warnings proposal, are more likely to rebel against confrontational methods intended to change health related behaviors. (Glynn and Moyers 2010). Motivation science, social and psychological reactance theory, and clinical and experimental studies all strongly caution against such provocative approaches (Steindl et. al., 2015). The unsolicited directing, telling, judging (shaming), or attempting to threaten through graphic warning labels on cigarette packs may especially affect those most pressure sensitive, rebellious younger individuals (Leffingwell et. al., 2007; Patten & Martin, 1996; Martin, 1996; Steindl, et. al. 2015; Glynn and Moyers 2010; Miller & Rollnick, 1991; 2002; 2009; 2013).

Clinical Experience

Over the decades of developing and leading smoking interventions, I transitioned from a state of the art behavioral and cognitive behavioral approach to one incorporating the newer research and findings on motivation science. When I started out as a psychologist, I helped create and operate a smoking treatment program for the most tobacco dependent smokers, termed the "treatment resistant smoker" (Martin, et al., 1997; Patten, Martin et al., 1998; Patten, Martin, et. al. 1999; Martin, et. al., 2000; Patten, Martin, et.al., 2001; Patten, Martin, et. al., 2002). These were chronic smokers with a high rate of relapse and many had tobacco related diseases. Our first sessions were filled with powerful information and education about smoking and tobacco, including pictures of diseased lungs and smokers' faces after cancer surgery. The result was a ninety percent drop-out rate. Through additional interviews, we found that the smokers were already aware of those risks and chose to avoid thinking about them to the point of rejecting, and becoming irritated by, the message as well as the messenger. After exhausting the various methods of educating and warning smokers about the harms of smoking with little success, we developed our own motivationally positive approach with much higher success rates, which was consistent with the counseling and communication approach called Motivational Interviewing (Miller & Rollnick, 1993; 2003; 2013; Martin & Sihn, 2009; Martin, Noto, & Walters, 2000; Martin, Walters, & Noto, 2000; Martin & Walters, 2002; Martin, 2003; Tilahun, & Martin, 2008; Martin et. al, 2008). Motivational Interviewing guided my more recent approach because of the essential failure of our efforts to inform, educate and "motivate" (i.e., force) smokers into quitting, including the use of vivid pictures and stories of the significant health and disease risks of chronic smoking.

In addition to my experience as a smoking treatment interventionist and community researcher, I have been involved in the marketing of our smoking programs and clinics, including writing and speaking (Martin, 1979; Frederiksen & Martin, 1978; Martin & Frederiksen, 1979; Martin, et al., 1980; 1983). During this period of recruiting and treating several thousand smokers to our clinics and programs, I employed motivational interviewing approaches to the marketing and recruiting of smokers, consistent with the science described above. We adapted our efforts and approach to the motivational science and interviewing style that attracted and reinforced smokers to doing something about their smoking, and at their own pace, with a flexible menu of approach choices. Our success (Martin, et. al., 1997) was based upon establishing rapport with the smoker, recognizing the strong role ambivalence plays in modifying unhealthy behavior, especially cigarette smoking, and working gradually and systematically but not forcefully with the smoker on their gradual, step-wise path to abstinence.

We learned rather quickly that the process of motivating smokers was complex and nuanced, and did not lend itself to fear appeals through graphic warnings and education, which served only to push smokers away, even to leaving the program with even lower self-efficacy and readiness for change. By incorporating the principles and style of motivational interviewing, and dropping the more confrontational approach I used when starting out, I was able to significantly increase my success rates in retaining and successfully treating smokers, which has continued over these many years.

Ultimately, communication and messaging regarding changing smoking behavior should be deeply respectful, empathic, and honoring toward the person's autonomy, freedom of choice,

Exhibit G

DECLARATION OF LAWRENCE R. BROOKS, MD

U.S. FOOD AND DRUG ADMINISTRATION – DOCKET NO. FDA-2019-N-3065

I, Dr. Lawrence R. Brooks, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am a physician, board certified in Internal Medicine, Pulmonary Medicine and Critical Care Medicine. I am licensed to practice medicine in California. I earned my medical degree from the Medical College of Virginia in Richmond, Virginia, in 1983. Next I completed an Internship and Residency in Internal Medicine at Beth Israel Medical Center in New York, New York, and served as Chief Resident (1986-87). I then completed a Fellowship in Pulmonary and Critical Care Medicine at Cedars-Sinai Medical Center in Los Angeles, California. I am currently a Pulmonary and Critical Care Intensivist at Sound Critical Care.

2. I was retained by Womble Bond Dickinson to review the proposed FDA label warning that reads: "WARNING: Tobacco smoke can harm your children" and the graphic image that accompanies that warning, which is reproduced below.

3. The proposed graphic image appears to depict a child (age 6-9, perhaps), wearing a hospital gown and with a mask over his mouth and nose. The child is pale and has red pigmentation under the eyes.

4. It is not clear that the graphic image is supposed to convey any particular condition. The extra pigment under the eyes makes the child look like he is both acutely and chronically ill. The picture shows a hospital gown, so it is more likely an acute episode. It is also possible that the red pigmentation under the eyes is intended to represent a child with allergies. Likely, the graphic image represents an asthma-related acute episode caused or triggered by exposure to tobacco smoke. Based on my clinical experience, this is a worst case scenario presentation: a child hospitalized due to an asthma attack caused by environmental tobacco smoke.

5. The picture shows a child wearing a mask. The mask is ambiguous. If it is supposed to be oxygen, then it's exaggerating. It would be uncommon for a child with an asthma attack to require oxygen. *If it is bronchodilators, then it is more realistic in that it would reflect a common treatment.*

6. By way of general background, the National Institute of Health's National Heart, Lung, and Blood Institute describes asthma as "a chronic, or long-term, condition that intermittently inflames and narrows the airways in the lungs. The inflammation makes the airways swell. Asthma causes periods of wheezing, chest tightness, shortness of breath, and coughing. People who have asthma may experience symptoms that range from mild to severe and that may happen rarely or every day. When symptoms get worse, it is called an asthma attack. Asthma affects people of all ages and often starts during childhood." [https://www.nhlbi.nih.gov/health-topics/asthma]

7. The incidence of asthma among children is approximately 1 in 12, or 8.3%. [CDC Vital Signs, www.cdc.gov/vitalsigns/childhood-asthma] [www.cdc.gov/mmwr]

8. Severe asthma attacks can be life-threatening and require a trip to the emergency room. The incidence of hospital admissions for a child with asthma is low; approximately 5-6% of children with asthma are hospitalized each year. [CDC Vital Signs, www.cdc.gov/vitalsigns/childhood-asthma] [www.cdc.gov/mmwr] The fraction of those cases potentially attributable to exposure to environmental tobacco smoke would be much smaller, because there are numerous other potential causes of such hospitalizations, including air pollution and exposure to allergens such as pollen and pet dander.

L Brooks MD

Lawrence R. Brooks, MD

Date: 9/27/19

Exhibit H

DECLARATION OF JONATHAN M. DAVIDORF, MD

U.S. FOOD AND DRUG ADMINISTRATION – DOCKET NO. FDA-2019-N-3065

I, Dr. Jonathan M. Davidorf, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am a physician, board certified in ophthalmology. I received my medical degree from the Univ. of California, San Diego School of Medicine in 1992. I completed a transitional internship at Harbor-UCLA Medical Center in 1993. I completed a residency in Ophthalmology at the Ohio State University, Havener Eye Center in 1996 and a fellowship in refractive surgery at Instituto Zaldivar in 1997. I have been engaged in private practice of general Ophthalmology in California, specializing in Cataract and Refractive Surgery since 1996. I have also been a Clinical Assistant Professor of Ophthalmology, UCLA School of Medicine, Stein Eye Institute since 1997.

2. I was retained by Womble Bond Dickinson to review the two proposed FDA label warnings that pertain to diseases of the eye along with the graphic images that accompany those warnings.

3. The first proposed FDA label warning I reviewed reads, “WARNING: Smoking causes age-related macular degeneration, which can lead to blindness,” and the graphic image that accompanies the warning is reproduced below.

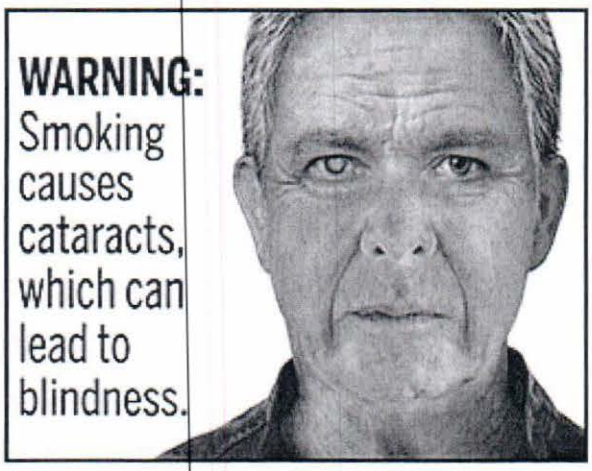
4. The proposed graphic image depicts the upper right portion of the head of an older-looking man. The man's right eye has been prepped with a speculum (eyelid retractor). There is a gloved hand holding a needle that appears to be poised to be inserted in the eye.

5. Currently, the most common and effective clinical treatment for wet Age-related Macular Degeneration is periodic intravitreal (into the eye) injection of a chemical called an "anti-VEGF." The proposed graphic image appears to be intended to depict this common treatment.

3. There are some inaccuracies in the graphic image. The needle that is actually used to inject the chemical into the eye is very fine, much thinner than the one depicted in the graphic image, and the needle is usually inserted in the lower outer area of the eye, not in the location shown on the graphic.

4. The most significant problem with the graphic image, however, is that (in part due to the inaccuracies described above) it may give rise to the false impression that the treatment is painful. It is not. The injection is preceded by numbing medication, and most patients feel only a slight pressure or nothing at all, while a few feel a moderate discomfort that lasts several seconds. My concern as a physician is the potential for frightening patients away from beneficial treatment.

5. The second proposed FDA label warning I reviewed reads, "WARNING: Smoking causes cataracts, which can lead to blindness," and the graphic image that accompanies the warning is reproduced below.



6. The graphic image appears to depict an older man with a very advanced cataract in his right eye.

7. The image is not a reasonable depiction of persons with cataracts in the US, because in the US the cataract would have been treated surgically long before it got to this stage. My experience in more than 30 years practicing ophthalmology, is that a very small percentage of cataract surgery patients in the US present with cataracts that far advanced.

8. Another concern is that the image makes the cataract look like a cosmetic problem. The man looks odd, because his eyes are asymmetrical. As a physician, I recognize that the discoloration in the right eye represents an advanced cataract. I cannot say that lay persons would necessarily recognize that; they may only see the cosmetic problem. The vast majority of patients who undergo cataract surgery in the US have cataracts that are undetectable by the unaided human eye; they can be detected only under the examination microscope.

Jonathan M. Davidorf, MD

Date: 9/23/19

Exhibit I

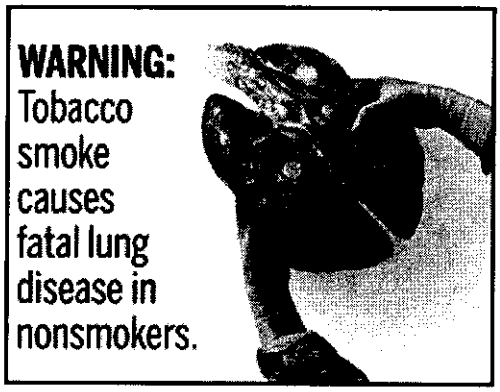
DECLARATION OF MARK O. FARBER, MD

U.S. FOOD AND DRUG ADMINISTRATION – DOCKET NO. FDA-2019-N-3065

I, Dr. Mark O. Farber, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am a physician, board certified in Internal Medicine and Pulmonary Disease. In 1967, I received my medical degree from Duke University in Durham, North Carolina. I completed an internship in internal medicine at the Indiana University School of Medicine from 1967-1968. I completed my residency in 1969 at Indiana University. I had a short hiatus in the military where I served as a flight surgeon after my internship and residency. Next, I completed a pulmonary research fellowship at Indiana University. I began as a Research Associate at Indiana University and then became an Assistant Professor of Medicine in 1973. I rose through the ranks and became a fulltime professor in 1988. I teach pulmonary critical care medicine to medical students, residents, and fellows. I diagnose and treat patients with chronic obstructive pulmonary disease ("COPD") and other pulmonary diseases. I have done so at the Indiana University School of Medicine and its affiliated hospitals since 1973. I am licensed to practice medicine in Indiana.

2. I was retained by Womble Bond Dickinson to review the proposed FDA label warning that reads, "WARNING: Tobacco smoke causes fatal lung disease in nonsmokers" and the graphic image that accompanies the warning, reproduced below.



3. The graphic image that accompanies the warning depicts what appears to be an artist's interpretation of a set of lungs and trachea. A pair of bloody, gloved hands is holding up the lungs, suggesting that this is an autopsy. The lungs are very black, and there multiple light-colored lesions on the surface of both lungs.

4. There are two major flaws in the graphic image that has been proposed to accompany the warning: the lungs do not look like a non-smoker's lungs, and the lesions are both ambiguous and inaccurate.

5. Black pigmentation in the lungs of smokers is caused by particles of tobacco smoke that are retained in the lungs. The amount of black pigmentation depicted in the graphic image would likely result from many years of heavy direct smoking. Exposure to environmental tobacco smoke alone would not result in this much black pigmentation. It would be very unusual to have lungs that look this black in a non-smoker.

6. The lesions on the surface of the lungs in the graphic image appear to be intended to depict lung cancer. The lesions are ambiguous; it is not clear to me as a physician that it is lung cancer. I cannot say what a lay person would interpret the lesions to be. Assuming that it is lung cancer, the location of the lesions is inaccurate. Lung cancer caused by exposure to environmental tobacco smoke would not be on the surface; it would be deep within the lung. Finally, bilateral multiple lesions of the size depicted

would be unusual for lung cancer that developed in a non-smoker. To me, as a physician, the graphic image depicts three different simultaneous cancers, which is not unheard of, but is certainly uncommon especially for ETS-related lung cancer.

Mark Farber, MD

Date: 09/20/19

Exhibit J

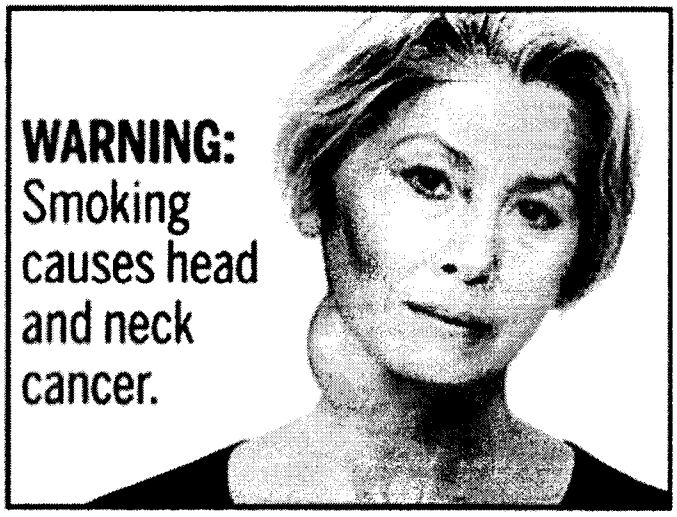
DECLARATION OF KIM R. JONES, MD, PhD

U.S. FOOD AND DRUG ADMINISTRATION – DOCKET NO. FDA-2019-N-_____

I, Dr. Kim R. Jones, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am a medical doctor, board certified in Otolaryngology. I received my medical degree from the University of North Carolina at Chapel Hill in 1986. I completed an internship in surgery and residency in Otolaryngology and Head and Neck Surgery at the University of North Carolina. I was an Assistant Professor of Otolaryngology at UNC from 1991 to 1998, Associate Professor with tenure of Otolaryngology in 1998, and an Adjunct Clinical Professor with the Department of Family Medicine at UNC from 1998-2015. I was in private practice from 1991-2015. I am licensed to practice medicine in the state of North Carolina.

2. I was retained by Womble Bond Dickinson to review the proposed warning label that reads, "WARNING: Smoking causes head and neck cancer," and the accompanying graphic image, reproduced below



3. The graphic image that accompanies the proposed the warning about head and neck cancer appears to depict an older woman with a very large lump or mass on her neck. It is not clear what the image is intended to represent. To me, as a physician, the lump on the woman's neck most likely represents a lymph node metastasis from a primary cancer elsewhere in the head or neck, such as the tongue.

4. I cannot say how the general public would interpret this proposed image. However, it seems unlikely that it would be accurately understood. If the general public were to interpret this proposed image as "what to look for" as a sign of head and neck cancer, then the image would be very misleading, as explained below.

5. There would be other signs of the cancer before the patient would develop a metastasis of the size and presentation in the proposed graphic image. A metastasis of that size implies an advanced stage of disease. To the extent that the proposed graphic image might be interpreted to mean that a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point, it would be misleading. In fact, if a patient waited until having a lump on her neck of that size and appearance before going to the doctor, the cancer would likely be too advanced for effective treatment. In my experience, as a physician in practice for many years, it would be extraordinarily rare for someone to wait to have a mass of that size before coming to the doctor.

K. R Jones

Kim R. Jones, MD, PhD.

Date: 9/18/19

Exhibit K

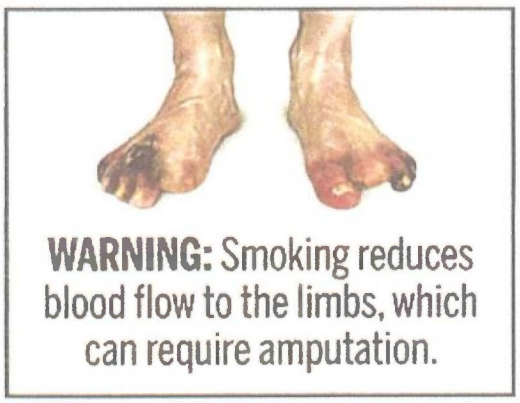
DECLARATION OF ROBERT WAGMEISTER, MD

U.S. FOOD AND DRUG ADMINISTRATION – DOCKET NO. FDA-2019-N-3065

I, Dr. Robert Wagmeister, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am a medical doctor and vascular surgeon in private practice in Santa Monica, California. I received my medical degree from the Tufts University School Of Medicine Boston, Massachusetts. I completed a Residency in General Surgery 1974-1977 at the Roosevelt Hospital, New York, N.Y. and 1977-1979 at St.Vincent's Hospital, New York, N.Y. I completed a fellowship in Peripheral Vascular Surgery at Newark Beth Israel Medical Center, Newark, N.J in 1980. I am board certified in Vascular Surgery and am licensed to practice medicine in California. I am a Fellow of the American College of Surgeons.

2. I was retained by Womble Bond Dickinson to review the proposed FDA label warning that reads, "WARNING: Smoking reduces blood flow to the limbs, which can require amputation" and the graphic image that accompanies the warning, reproduced below.



3. The graphic image that accompanies the warning appears to depict the feet of a patient with gangrenous toes and multiple toe amputations. The condition depicted is multi-limb; and the condition of the feet is fairly uniform, suggesting that both feet presented at about the same time. To me, as a physician, this depicts a condition known as Thromboangiitis obliterans (TAO), also called Buerger's disease. Buerger's disease is a nonatherosclerotic, inflammatory disease that most commonly affects the small to medium-sized arteries and veins of the upper and lower extremities. It is a specific type of peripheral vascular disease that is associated with smoking. The multi-limb presentation at about the same time as depicted in the graphic image is characteristic of Buerger's disease; multi-limb presentation as depicted in the graphic image is uncommon in the other types of peripheral vascular disease.

4. Buerger's disease is very rare, even in smokers. In my 40+ years as a practicing physician, I remember only a handful of cases of Buerger's disease. The National Institutes of Health (NIH) estimate the incidence of Buerger's disease in the US at 12-20 cases per 100,000 population. [National Institutes of Health, Genetic and Rare Diseases Information Center (GARD), "Buerger disease," https://rarediseases.info.nih.gov/diseases/5969/buerger-disease] I was unable to find any reported data for the incidence of Buerger's disease in US smokers. However, the estimated maximum or "ceiling" incidence in smokers can be calculated from the incidence rate in the general population by using the upper end of the population estimate and assuming that all cases of Buerger's disease occurred in smokers, The Centers for Disease Control and Prevention estimates that in 2016 about 15.5% of adults in the U.S. were current cigarette smokers. [CDC Press Release: "Smoking is down, but almost 38 million American adults still smoke", January 18, 2018, https://www.cdc.gov/media/releases/2018/p0118-smoking-rates-declining.html] An incidence of 20 cases per 15,500 smokers (15.5% of 100,000) translates to 0.1% of smokers with Buerger's Disease.

Thus the graphic image portrays a disease that likely would affect no more than 1/10 of 1% of smokers, that is 1 in 1000.

5. While I do not know how the public would interpret this image, to the extent that they interpret it as a common result of cigarette smoking among smokers, that interpretation would be inaccurate. There is nothing in the warning or imagery that conveys that the depicted condition is rare.

Robert Wagmeister

Robert Wagmeister, MD

Date: 09/20/2019.

Exhibit L

DECLARATION OF RACHAEL B. CLAXTON

U.S. FOOD AND DRUG ADMINISTRATION
DOCKET NO. FDA-2019-N-3065

"Tobacco Products; Required Warnings for Cigarette Packages and Advertisements."

I, Rachael B. Claxton, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

Introduction and Summary

1. I am Senior Vice President of R.J. Reynolds Vapor Company, and prior to January 1, 2019, held a variety of consumer marketing positions at R.J. Reynolds Tobacco Company ("Reynolds") and Santa Fe Natural Tobacco Company ("Santa Fe"), which is a sister company of Reynolds, as well as other affiliated and/or sister companies of Reynolds. I have more than thirteen years of experience in the field of consumer marketing. Over the course of my employment, I have held an array of consumer marketing positions. For example, I have served as the Senior Director, Regulatory Engagement – Consumer Marketing, and as Vice President for the Camel brand, and Director of Consumer Marketing, among other positions at Reynolds, and Vice President for Santa Fe's Natural American Spirit brand, and Director of Marketing Innovations at Santa Fe. Broadly speaking, my consumer marketing responsibilities have included overall brand strategic planning, product development, advertising, and marketing communications with consumers, including the packaging and point of sale marketing at retail, and consumer research. I hold a Master of Business Administration from Emory University's Goizueta School of Business, which I earned in 2007, and a Bachelor of Arts degree from Northwestern University, which I earned in 2002.

2. My statements in this declaration are based upon my personal knowledge, education, training, experience, and judgment as a senior executive of the entities with whom I have been employed and, as appropriate, are intended to apply to both Reynolds and Santa Fe.

3. Reynolds and Santa Fe firmly support further public awareness of the harms of smoking cigarettes, but also believe that the way those messages are delivered to the public cannot run afoul of the First Amendment protections that apply to all speakers, including Reynolds and Santa Fe.

4. Reynolds and Santa Fe market lawful products to adult tobacco consumers. Our ability to succeed in the marketplace depends on our ability to innovate and differentiate our brands from those of our competitors. Communicating with adult tobacco consumers is crucial to the companies' commercial success. No matter how skilled a company is at identifying products that respond to adult consumer preference, it will not succeed if it cannot tell its adult consumers (and its competitors' adult consumers) about them. Reynolds and Santa Fe therefore try to communicate with adult tobacco consumers about their brands, including how those brands are different from and are superior to competitive brands.

5. The proposed rule would require the FDA's graphic warnings to occupy the top 50% of every cigarette pack's front and back, and "at least" the top 20% of all brand advertising. The rule also would require the FDA's proposed messages on packaging to be displayed on a random basis for all brands and rotated on a quarterly basis in brand advertising. With respect to brand advertising, these messages would appear in virtually all branded consumer communications and media where we are permitted to advertise.

6. Reynolds currently manufactures and sells approximately 170 unique brand styles of cigarettes and Santa Fe has 13 unique styles of cigarettes. Each brand style has unique

communicate about it (including advertising and other forms of promotion, such as direct mail or email communications with consumers, sponsorship of events by the brand, etc.).

11. Beyond efforts to produce tobacco brands which meet the varied preferences of adult tobacco consumers better than offerings of our competitors, Reynolds and Santa Fe seek to communicate with adult consumers in a variety of ways about their brands and, in doing so, provide those adult consumers with relevant information about their brands. Marketing communications are essential in order to effectively compete in the marketplace. Marketing communications are our means of providing that information to adult tobacco consumers about our brand and product category offerings and to build brand equity (in other words, the overall value associated with our brand in the mind of the consumer).

12. When Reynolds and Santa Fe communicate with adult tobacco consumers, the primary goal is to differentiate their brands from competitors' brands. The companies strive to enable adult tobacco consumers to recognize their brands, to describe brand-specific features which may differentiate them from competitive choices and to convey to those adult consumers why their brands are superior to competitive brand choices.

13. Across all consumer-packaged goods, packaging is an important part of how manufacturers communicate with consumers, and packaging is an important consideration for consumers when making brand decisions. Packaging conveys important information to consumers, or reinforces messages conveyed in other media and most fundamentally differentiates one brand of a good from another. These principles apply with equal force in the cigarette category. The packaging in which our brands are sold is typically an integral component of our commercial communications with adult tobacco consumers (e.g., brand packaging is typically shown and is a prominent feature in marketing communications).

14. Cigarette packaging is extremely important to communication with adult tobacco consumers. It is what enables adult consumers to identify our brands, it seeks to communicate other salient information about our brands and, more fundamentally, it seeks to reflect and reinforce the character of the brand. Thus, it both represents and reinforces tangible and intangible aspects of what we refer to as brand equity, which means essentially what the brand stands for. Brand equity is reinforced through text, images, color and graphics, across communication media including, in particular, brand packaging.

The Proposed Graphic Warnings Rule Materially Impairs Brand Communications on Cigarette Packaging

15. All of these communication goals and tools and, in my judgment the overall brand equity, will be negatively impacted by the proposed rule given the amount of physical space being taken by FDA for its messaging, the physical placement of FDA's proposed messaging (top half of pack) literally subordinating *all* brand messaging to the FDA's messages and the redundancy of those messages (i.e., requiring an identical message on the pack front and back).

16. FDA states that this rule seeks to make its messages "prominent." In fact, the proposed rule renders the FDA's messaging the single most dominant feature of brand packaging by virtue of its placement, large size (both in an absolute sense and relative to discrete commercial elements), message imagery and redundancy. As such, it will unquestionably reduce our ability to communicate and reduces the effectiveness of our communication by virtue of (a) having less space to communicate, (b) lower prominence, (c) reduced ability to use text, images, color and graphics in the remaining less prominent display areas, and (d) the likelihood that consumers will not attend to our brand messages in an effort to avoid viewing the images chosen by FDA.

17. Moreover, the full impact of the current proposed rule must be considered in the context of other existing legal mandates regarding our packaging (discussed above, paragraph 7) and restrictions on content and location of our consumer marketing imposed by the federal law (discussed above, paragraph 8). In other words, the total impact of the proposed rule must be assessed in light of the fact that numerous other forms of brand communication and marketing directed to adult smokers have been expressly foreclosed to us or our use of them has been constrained under federal law. In addition, the proposed rule specifies that the text of words used in the warnings cannot be split when the package is opened, but FDA's proposed warnings notably do not layout the warnings in a consistent way, making it exceedingly difficult to implement this requirement in box packaging configurations.

18. The proposed rule will materially impair our ability to reinforce brand equity and convey information to adult consumers of cigarettes because it takes fully half of the primary physical space that we have for that purpose. Given the dramatically reduced amount of physical space available to us if 50% of the front and back of the package is occupied by a government message, existing trademarks must be redesigned, and the prominence, size, location of brand information and graphics, as well as the amount of information and graphics we are able to include on the package, will be adversely affected. Consider, for example, current Camel Classic Blue style packaging, reproduced below. The iconic Camel logo, used in various ways to identify the brand since 1913, in addition to other information identifying and describing the brand is prominent on the front panel.

be sure, that would also be true if FDA requires different (or random distribution) of the graphic warning messages on both the front and back package panels since an average adult smoker consumes 3-5 packs per week and thus would be exposed to all of FDA's messages, even if displayed on only one panel, within a short period of time.

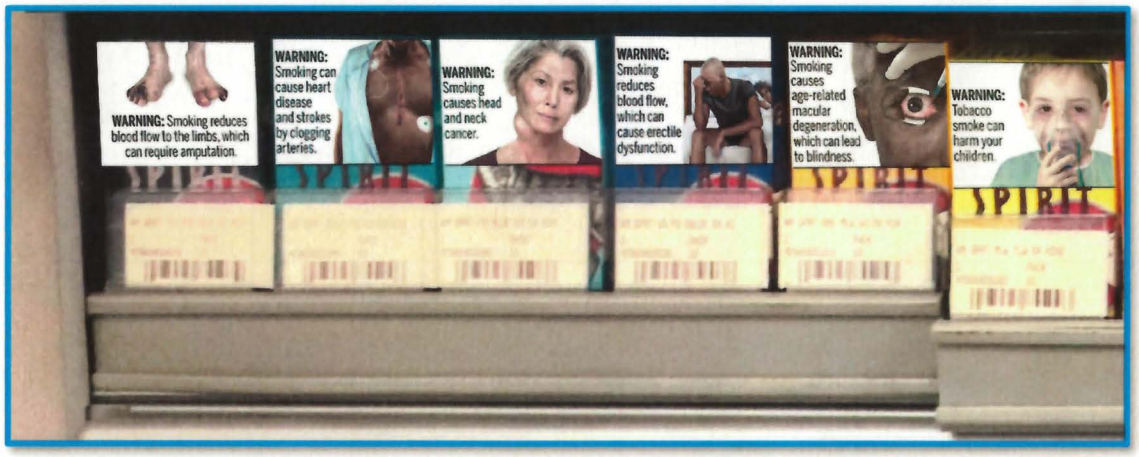
24. In addition to impacting our ability to communicate important information on brand packaging, FDA's proposed rule will also dramatically impact retail point-of-sale where adult consumers make brand purchase decisions. By way of background, virtually all retail sales of cigarettes in the U.S. are not self-service, in other words the consumer does not physically select a pack or carton to purchase from the merchandising display. Typically, there is a merchandising display that contains the brands being sold at that location, it is several feet behind the sales counter (e.g., 5' to 7'), and it is solely accessed by a store clerk in response to an adult consumer's request. The primary information being conveyed at retail point-of-sale is brand availability (primarily based on the physical visibility of the cigarette packages themselves) and price (such as on shelving "channel strips," i.e., a 2" wide strip of paper bearing the brand name and/or price). Point-of-sale may include a few larger pieces with some brand imagery, but these are also typically are focused on promoting brand availability. If these pieces are larger than 36 square inches a 20% graphic warning message will be required, further relegating brand messaging to a less prominent location in this medium as well.

25. The relegation of brand imagery to the bottom half of a cigarette package further harms our ability to communicate with adult consumers because consumers in a retail outlet may not be able to see the brand name of the product when it is in the merchandising fixture. As described above, if our packaging has 50% less space for conveying messages and are viewed from several feet away, brand messages -- if physically visible at all -- would be illegible, and

hence, invisible. Moreover, it is not possible to mediate the impact of the rule by adding point-of-sale signage since doing so would block clerk access to brands available for purchase.

26. At my direction, I obtained photographs depicting retail trade marketing displays of primarily Reynolds and Santa Fe brand cigarettes to reflect the impact of the FDA's proposed rule (i.e., packs bearing random graphic warnings on the top 50% of the packs and, yellow shading reflecting other required graphic warnings occupying the top 20% of the point-of-sale messaging that qualifies as advertising under FTC guidelines):

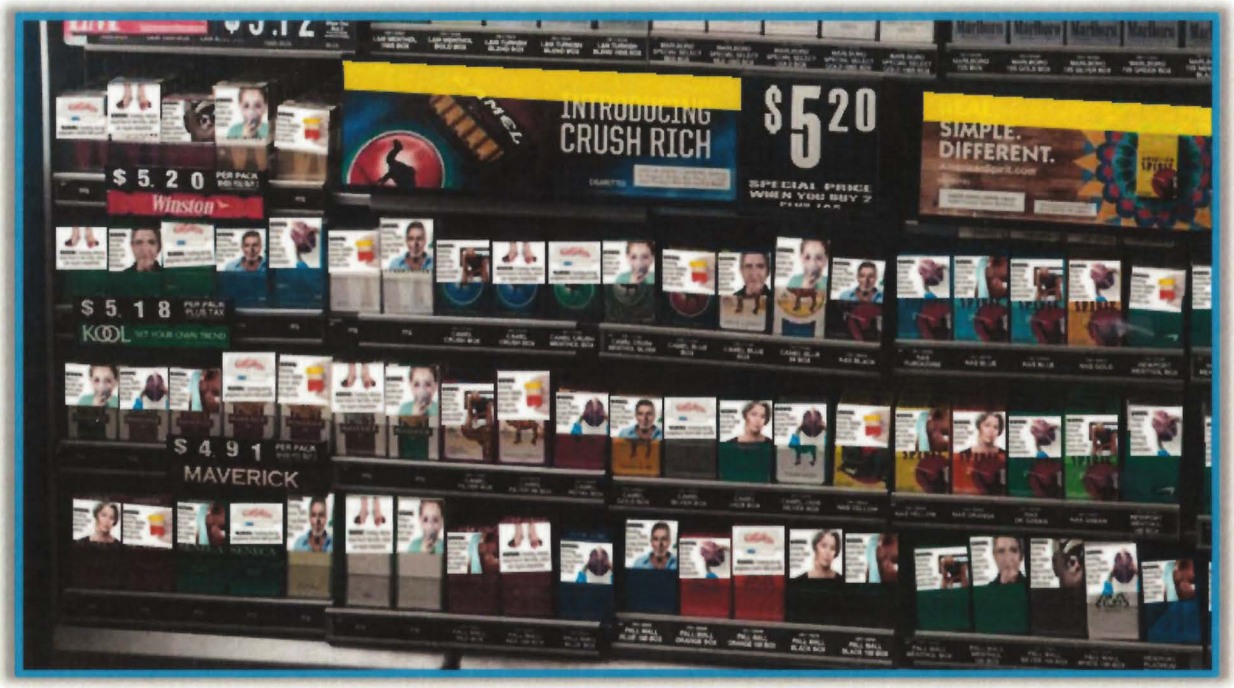
Current Retail Display



Modified Retail Display Reflecting Proposed FDA Rule

These graphics above illustrate the impact of the proposed rule in a typical retail environment; predictably, the FDA messages are collectively dominant, and branding has become invisible.

Current Retail Display



Modified Retail Display Reflecting Proposed FDA Rule
(Yellow Shading Reflects Additional 20% Required Graphic Warnings)

Finally, as illustrated below, this graphic reflects a typical merchandising unit for cigarettes at retail and how, as a result of the proposed rule, it would be impacted.

Modified Retail Display Reflecting Proposed FDA Rule
(Yellow Shading Reflects Additional 20% Required Graphic Warnings)

Consequently, in the modified environment reflecting the propose rule, the dominant message for consumers will be only the FDA's proposed messages.

The Proposed Graphic-Warnings Rule Also Impairs Cigarette Advertising Brand Communications

27. Under the proposed rule, each advertisement for cigarettes must bear a graphic warning on the top 20% of the advertisement, including messages at point-of-sale where the FDA message would be dominant, as illustrated above. It is unclear why this further message redundancy is necessary, but it reflects a further material reduction in the space that manufacturers have to communicate with adult consumers at retail where messaging

opportunities on point-of-sale are limited (typically to brand name and price) due to the nature of the retail environment.

28. The proposed rule again takes the most prominent portion of advertising space, the top 20% of each advertisement, for FDA's proposed message, irrespective of the amount of space needed to merely communicate it. Thus, the proposed rule would have much the same effect on cigarette advertisements that it has on cigarette packaging: the warnings would either distract consumers from Reynolds's message or repulse consumers and potentially cause them to avoid looking at brands' messages at all.

29. Moreover, given that the rule requires the FDA messages to appear on all advertising at retail, it further results in the display of duplicative messages with no regard to whether such duplication is necessary to convey the information sought to be conveyed.

30. I end where I began. Reynolds and Santa Fe firmly support further public awareness of the harms of smoking cigarettes, but also believe that the way those messages are delivered to the public cannot run afoul of the First Amendment protections that apply to all speakers, including Reynolds and Santa Fe. These companies market lawful products only to existing adult tobacco consumers. Communicating with adult tobacco consumers is crucial to Reynolds's commercial success. If this rule is implemented as proposed, our ability to do so will be significantly undermined.

Rachael B. Claxton

Oct. 9, 2019

Exhibit P

KING & SPALDING

King & Spalding LLP
1180 Peachtree Street N.E.
Atlanta, GA 30309-3521
Tel: +1 404 572 4600
Fax: +1 404 572 5100
www.kslaw.com

Caitlyn J. Ozier
Direct Dial: +1 404 572 4654
Direct Fax: +1 404 572 5100
cozier@kslaw.com

June 14, 2017

Filed Electronically

Division of Freedom of Information Offices
Center for Tobacco Products
Food and Drug Administration
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Dear Sir or Madam:

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552 (as amended), we respectfully request an electronic mail version, CD-ROM, or DVD copy of the records and documentation described in more detail below from the U.S. Food & Drug Administration (FDA) pertaining to the qualitative and quantitative testing being done by FDA with regard to Section 201(a) of the Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776 ("Tobacco Control Act"), to require cigarette packages and advertisements to bear color graphic images and specified textual warnings.

Regarding each of the numbered items below, we respectfully request all Documents (or Qualitative or Quantitative Research Documentation, where specifically noted) reflecting, describing or related to:[1]

1. The initial phase of activities (beginning in 2013 and ending in 2015) of the FDA working group established in 2013 to develop a new proposed rule implementing Section 201(a) of the Tobacco Control Act (the "FDA Working Group"), including:

    a. The selection of the members of the FDA Working Group. *See* Declaration of Mitch Zeller, Paragraph 12, in *American Academy of Pediatrics et al v. United*

[1] *See* Attachment A for definitions of "Documents," "Communication," "Qualitative Research Documentation," and "Quantitative Research Documentation," as used throughout this request.

States Food and Drug Administration, No. 1:16-cv-11985-IT (D. Mass.) (May 26, 2017) (hereinafter "Zeller Declaration").[2]

b. The "extensive review of literature and data to determine the most appropriate research goals for a new rulemaking" regarding graphic health warnings. *Zeller Declaration, Paragraph 12*.

c. The selection of "outside experts" and any related Communications with these "outside experts" regarding the "extensive review of literature and data to determine the most appropriate research goals" for a new graphic warning rulemaking. *Zeller Declaration, Paragraph 12*.

d. FDA's determination "that it would modify the text of the warning statements in the TCA" based on the review of literature and data, as well as Documents related to these warning statements developed by science staff and "medical and epidemiology staff review [of] the [graphic health warning] statements to ensure their accuracy." *Zeller Declaration, Paragraph 13.*

e. Selection of, and consultation and Communications with, "outside experts to review proposed study designs." *Zeller Declaration, Paragraph 13.*

f. Completion of the "initial phase" of the FDA Working Group, including information regarding conclusions of the work done by the FDA Working Group up to that point in time. *Zeller Declaration, Paragraph 13.*

2. Information regarding FDA's evaluation of the text and images for the new proposed rule, including:

a. FDA's "overall research plan for evaluating the text and images for the [new proposed] rule." *Zeller Declaration, Paragraph 14.*

b. "Qualitative testing" of the modified warning statements, including testing in "16 focus groups in three locations." *Zeller Declaration, Paragraphs 14 and 15.*

c. Communications with the "firm with expertise in social science research" that FDA contracted to conduct these focus groups. *Zeller Declaration, Paragraph 15.*

d. All Qualitative Research Documentation (see Attachment A) related to "qualitative testing" of the modified warning statements, including:

i. The purposes, goals, and scope of the qualitative testing. *Zeller Declaration, Paragraphs 14 and 15.*

[2] The term "Zeller Declaration" refers to the Declaration of Mitch Zeller filed on May 26, 2017 in the matter of *American Academy of Pediatrics et al v. United States Food and Drug Administration*, No. 1:16-cv-11985-IT (D. Mass.) A copy of the declaration is included as Attachment B.

ii. Establishment of the four "aim[s]" of the testing. *Zeller Declaration, Paragraph 15* ("The aim of this qualitative testing was to assess: (a) consumer knowledge, beliefs, and misperceptions related to cigarettes and cigarette smoking; (b) general impressions about cigarette package warnings; (c) knowledge and beliefs about the health consequences of smoking presented in modified warning statements; and (d) attitudes toward the sources of the warning statements.").

3. FDA Working Group's revision of the modified warning statements in the fall of 2015 "based on the findings of this [qualitative] testing." *Zeller Declaration, Paragraph 15.*

4. Information regarding translation of the modified warning statements into Spanish, including:

   a. Translations of the modified warning statements into Spanish. *Zeller Declaration, Paragraph 16*.

   b. Information on the "nine in-person cognitive interviews," including the purposes, goals, and scope of the qualitative testing of the Spanish translations. *Zeller Declaration, Paragraph 16* ("CTP then conducted nine in-person cognitive interviews with Spanish speakers to: (a) determine participants' comprehension of the modified warning statements; (b) identify further opportunities to refine the translation; and (c) gather feedback from Spanish-speaking participants on health conditions and terminology used.").

   c. Qualitative Research Documentation (see Attachment A) related to the "nine in-person cognitive interviews" that were completed in early 2016. *Zeller Declaration, Paragraph 16*.

5. FDA's development of new images for the graphic warnings, including:

   a. Selection of the "communications and marketing firm" in February 2015 to "develop new images" for the graphic warnings. *Zeller Declaration, Paragraph 17*.

   b. Development of a "conceptual direction" for the new warning images. *Zeller Declaration, Paragraph 18*.

   c. Review of the "[i]nitial image concepts" by "FDA medical and science staff to ensure that the concepts accurately depicts health conditions attributable to smoking." *Zeller Declaration, Paragraph 18*.

   d. Qualitative testing of the "image concepts," including:

      i. Information regarding the "54 in-person, in-depth interviews in three locations." *Zeller Declaration, Paragraph 19.*

ii. All Qualitative Research Documentation (see Attachment A) related to the qualitative testing of the "image concepts." *Zeller Declaration, Paragraphs 18 and 19.*

iii. The purposes, goals, and scope of the qualitative testing of the "image concepts." *Zeller Declaration, Paragraphs 18 and 19.*

e. The "preliminary suggestions for modifying the image concepts" made by the "communications and marketing firm." *Zeller Declaration, Paragraph 20.*

f. "Further suggestions of image enhancement to ensure accuracy and consistency with scientific, policy, and legal considerations" made by FDA. *Zeller Declaration, Paragraph 20.*

6. Finalization of the graphic warning images by a certified medical illustrator, including the actual images. *Zeller Declaration, Paragraph 22.*

7. Information regarding FDA's plans to conduct a final qualitative test of the images, including:

a. The plan to present the images to "20 focus groups in four locations." *Zeller Declaration, Paragraph 23.*

b. Qualitative Research Documentation (see Attachment A) related to FDA's "plans to conduct a final qualitative test of the images." *Zeller Declaration, Paragraph 23.*

c. The purposes, goals, and scope of FDA's "plans to conduct a final qualitative test of the images." *Zeller Declaration, Paragraph 23.*

8. Information related to Quantitative testing to assess the statutory and the modified warning statements, including:

a. The "first of two quantitative studies" anticipated to involve "2,500 participants from various groups of consumers." *Zeller Declaration, Paragraph 24.*

b. The "final quantitative study" anticipated to involve "6,900 participants to view and answer questions about graphic health warnings on mock cigarette packages and advertisements." *Zeller Declaration, Paragraph 29.*

c. Quantitative Research Documentation (see Attachment A) related to the quantitative testing assessing the statutory and modified warning statements. *Zeller Declaration, Paragraphs 24-29.*

d. The purposes, goals, and scope of the "two quantitative studies" assessing the statutory and modified warning statements. *Zeller Declaration, Paragraphs 24-29.*

9. How FDA has measured or intends to measure if the proposed graphic warnings affect understanding of the harm associated with smoking cigarettes and whether any such difference is material, or whether any such difference affects individual behavior related to smoking initiation, continued smoking, smoking cessation, or any other behavioral endpoint.

10. Evaluation of the impact of graphic warnings on cigarette packaging on cigarette smoking prevalence.

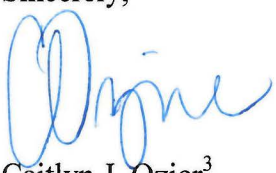
* * * * *

In the event that we are denied any document or any portion of any requested document, please provide all other documents that are responsive and not subject to an exemption or any reasonable, segregated portion of a responsive record after the redaction of any alleged exempt material. See 5 U.S.C. § 552(b). Please identify each document with particularity and specify the statutory basis for the denial and the factual support for the denial.

In addition, we will accept separate responses to this request for each of the 10 numbered items above. Indeed, we respectfully request that FDA send the responsive records for each of these numbered items as soon as the records are available, and not wait until responsive records have been collected for all of the 10 items requested above.

We are willing to pay reasonable charges incurred for appropriate search and copying of these documents upon presentation of an invoice along with the documents. We authorize fees for this request up to a maximum of $5,000.00. If you estimate that the search and copying fees will exceed this limit, please inform me in advance by telephone (404) 572-4654 or email cozier@kslaw.com.

Sincerely,



Caitlyn J. Ozier[3]
King & Spalding LLP

[3] **Admitted in MO and DC; practice directly supervised by principals of the firm**